UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Case No. 08 CV 1490-AKH

DREW SCIENTIFIC, INC.,
Plaintiff/Defendant-in-Counterclaim
vs.

POINTCARE TECHNOLOGIES, INC,.
Defendant/Plaintiff-in-Counterclaim

AFFIDAVIT OF W. PETER HANSEN IN OPPOSITION TO PRELIMINARY INJUNCTION

I, W. Peter Hansen, Ph.D., declare:

1. I am Chief Scientific Officer of PointCare Technologies, Inc. ("PointCare"). I make this Affidavit on personal knowledge, except where specifically stated.

HIV/AIDS Background

2. In order to explain the HIV/AIDS diagnostic instruments at the core of this lawsuit, I will begin with a short discussion of HIV/AIDS. Two critical discoveries were made concerning AIDS very shortly after the syndrome came upon the world scene in the early 1980s. The first was that AIDS is the end stage of an infectious disease caused by the HIV virus. The second was that five to seven years after being infected by the virus, most HIV patients experience a sudden loss of a certain type of white blood cells. These white blood cells are called CD4 lymphocytes or T-Helper lymphocytes. Losing these white cells marks the point in time when HIV patients begin to acquire other infections, such as tuberculosis. While serious, these infections usually can be treated and cured. When superimposed on an HIV infection, however, it was found that these infections meant certain death. The CD4 lymphocyte subclass

is now known to be one of the body's key defenses against life threatening infections. The loss of this subclass essentially paralyzes immunity.

3. After these discoveries, there was a full decade of medical despair when all known anti-viral drugs failed to cure, or even stem, the course of the disease. In the early 1990s, a breakthrough occurred. It was shown that certain, already known, anti-viral drugs did indeed stem the course of the disease if the drugs were administered when a patient's CD4 lymphocyte "count" had dropped to about 200.[1] Today, physicians use 200 to 350 as the count range where drugs should be started. Triggering the start of therapy from the CD4 lymphocyte count, and using the CD4 lymphocyte count to tell the physician that the virus has become drug resistant and a therapy change is needed has added twenty years or more to the life expectancy of HIV/AIDS patients.

4. Tests for counting CD4 lymphocytes are just as important as drugs in the worldwide HIV/AIDS effort. In fact, without first getting a "CD4 count", administering HIV drugs to a patient is a useless and sometimes even dangerous practice.

PointCare Background And Mission

5. In 2002, after my wife Dr. Petra Krauledat and I had retired from business, medical colleagues approached us about HIV/AIDS. They told us that CD4 counting was essentially unavailable to patients living in rural environments in the developing world. This amounted to about 2/3 of the 40 million HIV infected people worldwide. We traveled to several English-speaking southern African countries so that we could go into deep rural areas and speak directly to caregivers and patients alike and assess the situation for ourselves.

[1] Blood cell counts refer to the number of cells in a cubic millimeter of blood. So a count of 200 means 200 CD4 lymphocytes per cubic millimeter of blood.

6. We were impressed by two facts almost immediately. First, we found that world charitable efforts had successfully brought affordable HIV drugs to even the most remote clinics. In other words, the drugs were finally there. Second, our colleagues had been right; there was almost no CD4 counting equipment available. Once in a while, we saw a charitably donated CD4 counter in a corner under a dust cover and not being used. That was a surprise that we set out to understand as I will now explain.

7. CD4 counting is performed by instruments that count CD4 cells that have been "marked" by chemicals so that the CD4 cells can be distinguished from other blood cells. The chemicals (sometimes called reagents) used to mark CD4 cells need to be kept at refrigerator temperatures and out of bright light at all times. Most importantly, this means that a so-called reagent "cold chain" must be kept unbroken during shipment from the factory to the clinic. Clinic after clinic told us of tens of thousands of dollars worth of chemicals that had been destroyed by the extreme heat of southern Africa. Delays in customs, misdirected shipments, power outages that lasted days and ruined everything in the refrigerator, and the fact that most clinics had no refrigerator, meant to us that a heat resistant CD4 marking chemical needed to be invented, and fast.

8. These insights were the beginning of PointCare. We decided that our first job was to revolutionize the chemistry that was used to mark CD4 cells, and create a new marker that could stand heat. We returned to the United States, used part of our retirement savings, and, drawing upon our lifelong careers as inventors and scientists, together developed that marker. It is called CD4Sure™ "immunogold." The method of marking cells and counting them is called the CD4Sure™ "assay."

The New CD4 Marker (Immunogold) And The PointCare Assay

9. Blood tests are diagnostic "assays." A diagnostic assay in blood includes the chemicals and the steps to use them in detecting a constituent or property of blood. For example, a blood glucose test for diabetics is an "assay for blood sugar" that uses a chemical to turn blood a certain color on a chemically treated white piece of paper. The color is detected by a hand-held, light sensitive instrument. Color is related to the amount of sugar by a small computer inside the instrument. The calculation used by the computer to convert "color" to a number for "blood sugar amount" is sometimes called an "algorithm."

10. In 2003, PointCare invented a new assay for CD4 cell counting that was particularly suitable for the developing world.

11. Before PointCare, there was a 25 year old assay by which CD4 counting was done for kidney transplant patients. HIV was unknown at the time. I co-invented the basic elements of this assay when I worked for Johnson and Johnson. I will call it the "traditional" CD4 assay. Under licenses from Johnson and Johnson, many companies manufactured chemicals and a method of use (assay) based on this invention. Variations on this "traditional" assay are standard methodology today.

12. The "traditional" CD4 assay uses a chemical "paint" that sticks only to the surface of CD4 cells. This special biological "paint" emits light (glows) when struck by a laser beam. A very skilled technician follows a step-by-step method of mixing the CD4 "paint" and various other chemicals with human blood under exacting conditions of temperature, time, and mixing. When carried out correctly, this process selectively makes the CD4 cells in a patient's blood sample glow under laser light.

13. This was not enough, however, to make the traditional CD4 assay work. An instrument was needed to count the glowing cells. "Flow cytometers" are instruments that can use a laser to detect and count cells that glow. A "traditional" CD4 assay and a flow cytometer can be used to give a CD4 count for a patient's blood. In fact this is the most common method today.

14. The weak link in the traditional assay is that the chemicals that make the paint "glow" under laser light decompose rapidly in even mild heat (room temperature) and no longer work. In fact, they can only be out of the refrigerator for minutes at a time. To further complicate matters, the "paint" fades under room lights, and therefore can only be exposed to room light for minutes at a time. Cold temperatures and dim light are not the usual conditions in those places where HIV is prevalent. The deployment of the "traditional" assay for CD4 counting has been a problem in just those places that need it most.

15. In inventing its new CD4Sure™ assay, PointCare began with a new paint that was heat resistant and light resistant and a method by which it could be used to count CD4 cells. The new paint that uses microscopic particles of gold of a special size to make a "reflecting paint" rather than a "glowing paint." We discovered that when a CD4 cell was covered with gold "paint," it reflected laser light very intensely and could be detected over other cells and counted by a flow cytometer. Most importantly, we discovered that we could freeze-dry the gold-antibody paint and have it work when it was reconstituted with a simple liquid. The old style "glowing" paint was destroyed by freeze-drying so it could not be preserved and protected this way. When freeze-dried, this new paint could stand temperatures of 120 Fahrenheit for a few days, and 110 Fahrenheit for almost a year. It was also completely stable in bright light including equatorial sunlight. These breakthroughs solved the problem of shipping and storage

to the developing world. PointCare refer, to its new CD4 cell paint as "Immunogold" and the method of use as the PointCare CD4Sure™ assay.

16. As part of its CD4Sure assay, PointCare also invented a method to use a chemical that we call an "accelerant" to shorten the sample preparation time to as little as sixty seconds. This invention makes the PointCare assay the fastest CD4 test in the world.[2]

17. With the traditional CD4 method, the procedure takes so long that patients get their results days to weeks later. With the PointCare assay, a patient who had walked for miles to get tested could have the result immediately. Imagine a debilitated AIDS patient walking ten miles twice to get tested and then twice more to get their results. Imagine sending someone from a clinic out into the bush to try and find the patient to give them their results. We eliminated these problems and enabled clinicians to test the patient, counsel them on the next steps in their life, change their drugs if necessary, detect and treat their other diseases, all in less than a twenty minute session.

PointCare's First Medical Device, The AuRICA

18. The instrument we developed to perform the CD4Sure™ assay is named "AuRICA."[3]

19. The U.S. Food and Drug Administration (FDA) approved the AuRICA instrument and CD4Sure™ assay in November 2004.

20. PointCare made rapid progress toward its mission of inventing and commercializing an HIV/AIDS diagnostic instrument viable for rural areas of developing nations. It took PointCare only two years to incorporate and build a company from zero staff, attract outside investors, , invent the CD4Sure™ assay, build manufacturing capacity, build a

[2] On April 21, 2008 the United States Patent and Trademark Office notified PointCare that its patent application for the CD4Sure assay is being allowed. I expect the patent will be published in approximately six months.
[3] Its original name was PointCare "Flowcare."

sales and service team, test the product, and get FDA clearance for the AURICA and CD4Sure™ assay.

21. It took PointCare 18 months to develop the AURICA and CD4Sure™ assay (May of 2003 to November 2004). This was an 18 month timeline for a completely new technology; one that needed first to be invented.

22. The AURICAwas based on an instrument that IDEXX Laboratories in Westbrook , Maine manufactured for veterinary use. PointCare made some mechanical and electrical changes to the IDEXX instrument and wrote new software for it with these changes, , the IDEXX instrument could run the PointCare CD4Sure™ assay.

23. The assay was completely automated. The user took a tube of blood with the cap still on it and simply put the tube in a slot, closed the door, pressed "run" and came back minutes later to see the CD4 result. There were no "manual" chemical steps to perform. This level of full automation meant that people with almost no training could run the assay. This automation was another very important PointCare invention to serve the developing world.

24. IDEXX signed an agreement to manufacture and sell the modified instrument to PointCare. In 2005, IDEXX changed its entire upper management and its commitment to PointCare's mission. Following this change, the quality of the product manufactured for PointCare deteriorated to the point where most instruments shipped to PointCare were no longer acceptable. PointCare rebuilt every instrument that it received from IDEXX. IDEXX refused to correct the problem and refused to ship further instruments because PointCare demanded the original quality standard in future shipments. PointCare rebuilt the approximate 65 instruments it had already purchased from IDEXX, delivered them to customers in five developing world countries, and stopped working with IDEXX in or about the fall of 2005.

25. While Pointcare served approximately 100,000 patients with 65 AuRICAs, this was far below our plan, and far below the need (there are close to forty million HIV infected people in the developing world). PointCare was faced with a business emergency and was also in danger of not delivering on the hope that we had generated around the world.

PointCare Looks For An AuRICA Replacement

26. In November, 2005, Petra Krauledat, Daniel O'Connor (PointCare's then-Vice President of Sales) and I attended the Medica Conference in Düsseldorf, Germany to search for instrument manufacturers that could help us replace the IDEXX instrument in the shortest time possible. The replacement would have to run the PointCare CD4Sure™ assay.

27. We interviewed several manufacturers including Drew. The Drew representatives (Drew President Harry Rimmer, Vice President for Sales and Marketing Frank Matuszak and a senior Drew technical representative, Roger Bouree) showed us their FDA approved, Excell 22, an automated hematology counter.[4]

28. We told Drew's representatives about our parting of the ways with IDEXX, and PointCare's pressing need to find a manufacturer who could quickly develop, and bring to market, a CD4 counter instrument compatible with PointCare's existing CD4Sure™ assay. Discussions proceeded with that explicit understanding.

29. Mr. Bouree and I then began a detailed discussion about the PointCare CD4Sure™ assay, PointCare's current machine the AuRICA, and the Drew Excell22. These discussions took place over the course of two days at Medica in Dusseldorf. Mr. Bouree and I agreed that two additions would need to be made to the basic Excell 22 in order to process the CD4Sure™ assay.

[4] A hematology counter counts blood cells. For example a hematology counter would give a red blood cell count and a white blood cell count. Some advanced hematology counters can measure other blood cell properties.

30. These two additions are as follows. First, the Excell 22 "optical cytomer"[5] would need an additional light detector. Second, a new fluid-handling module that he and I called the "CD4 module" would need to be added. I will now explain what they are.

31. The Pointcare AuRICA and the Excell 22 both had optical cytomerters. I made sketches and showed Mr. Bouree how the AuRICA optical cytometer worked. He and I agreed that we needed to add one more light detector to the Excell22 optical cytometer and it would accommodate the CD4Sure™ assay while continuing to perform all the Excell 22 cell counts. We agreed that this was a key hypothesis to test. We also agreed that if it woked, there would be only a short time needed to put the modified Excell 22 optical cytometer into production.

32. Our plan was that Mr. Bouree would modify an Excell 22 optical cytometer, and together he and I would see if the CD4Sure™ assay worked on it.

33. Mr. Bouree and I also discussed the second addition needed to the Excell 22 in order to accommodate the CD4Sure™ assay. It was a mechanical module for moving the blood sample, adding CD4Sure™ chemicals, mixing and heating the combination of blood and CD4Sure™ chemicals, and then passing the mixture to the optical cytometer for cell counting. We called this module the "CD4 module". I showed Mr. Bouree how the AuRICA used a computer driven needle and syringe principle to move blood and deliver CD4Sure™ chemicals. The AuRICA also had a mixer and heater that met the CD4Sure™ requirements. The AuRICA principle had been proven to work in the field. Mr. Bouree said that Drew knew how to make such a mechanical module. This confirmed my thoughts that we would be combining AuRICA and Excell technology and not inventing new technology.

[5] An "optical cytometer" is a module within a larger machine that uses light and light detection to classify and count cells.

34. I gave Mr. Bouree a detailed explanation of how Drew's instrument needed to work with the CD4Sure™ assay with no substantial modification to the assay. For the Excell22 to perform the CD4Sure™ assay, the Drew CD4 module would need precisely to measure out and mix the PointCare assay chemicals with blood and, then heat the mixture to 37 degrees Celsius (98.6 Fahrenheit) for 1 to 3 minutes. After a step that removed red blood cells that I also described, the modified optical cytometer would be able to count the CD4 cells in the blood.

35. Mr. Bouree told me that Drew had an experienced engineering staff and a strong experimental machine shop that designed and developed mechanical modules for new products and that they could design a CD4 module. He was open to using the AuRICA computer driven needle and syringe principles for this module.

36. Mr. Bouree and I agreed that the most important place to start was to assess the feasibility of his idea to modify the Excell22 optical cytometer to fit the PointCare CD4Sure™ assay. If there was an incompatibility here, then the project would not be worth pursuing. If this critical test worked, we agreed the rest of the project should go quickly. Mr. Bouree said that he was the optical cytometer expert at Drew; the stock and trade of the rest of Drew engineering was to make the pumps, valves, mixers and heaters needed for the CD4 module. After Medica, I understood that Mr. Bouree went back to Drew to make his modification to the optical cytometer.

C2 Diagnostics

37. After Medica, I went to Montpellier, France and interviewed C2 Diagnostics, another instrument manufacturer. I determined that they could make an instrument that would work with a modified CD4Sure ™ assay. This option appeared to be a riskier and lengthier project that working with Drew. I say this because the optical cytometer in the C2 instrument

was very different from the one in the AuRICA. Unlike the project with Drew the CD4Sure assay would need modification to work with this optical cytometer. The reward, should the project with C2 work, was that the product would be small and portable. The large Drew instrument would need to be in a stationary hospital lab but it would process more patients in a day. Small size and portability are important features in serving rural populations and patient throughput it is important in hospital labs. The instrument with C2 became known as the "NP," short For "Near Patient." The assay that PointCare developed for the NP is called PointCare NOW™. They were designed to be complimentary and not competitive.

PointCare Starts Work With Drew

38. Drew asserts on page 2 of its Brief that *PointCare* conducted a feasibility study. This is false and misleading. PointCare and Drew *jointly* carried out feasibility studies. Drew produced in this litigation a Test Report concerning feasibility testing of the modified Excell22 optical cytometer and PointCare CD4 assay authored by Mr. Bouree and dated January 5, 2006. See Exhibit 1 hereto (DR28256-28257), a true copy of a test report created by Drew and produced in discovery. Mr. Bouree's Test Report clearly states that the participants in the feasibility testing were Mr. Bouree, Mr. Barry and myself.

39. From January through March 2006, Drew and PointCare jointly conducted feasibility studies for the HT.

40. I went to Drew twice in the January-March 2006 time frame; once with Don Barry of PointCare, and once again with Romiya Glover of PointCare. Both times we worked directly with Mr. Bouree in a Drew laboratory.

41. All four of us agreed that the PointCare CD4Sure™ assay worked with the optical cytometer that Mr. Bouree had modified to be like the AuRICA. The modified optical cytometer was mounted in an old Excell22 that I called the "feasibility Excell22."

42. Mr. Bouree, Mr. Barry, Ms. Glover and I reviewed the data that the feasibility Excell22 generated. We agreed that the feasibility Excell22 was putting out good data that could be "recognized" and analyzed by a computer. This realization was good news for a fast project, because the "crown jewel" of the existing software in the AuRICA (the "CD4 algorithm") could be "pasted" into the new product (rather than having to create a new algorithm).

43. Drew also asserts in its Brief on page 2 that Drew relied on *PointCare's* findings during these feasibility studies. This is false and misleading. Mr. Bouree wrote to the Drew President, Harry Rimmer, on February 12, 2006 and summarized the feasibility testing He wrote, "It would be very easy to modify DREW optic head to read both 45 and 90 degree." He ended by writing, "This is definitely a project worth doing as this parameter is only offered on top of the line hematology analyzers (>100K) or dedicated flow cytometers." See Exhibit 2 hereto (DR19345-47), a true copy of the email Produced in discovery.

44. Mr. Barry submitted a formal, 23 page feasibility report on March 27, 2006. I emailed it to Mr. Bouree a few days later. See Exhibit 3 hereto, a true copy of Exhibit 1 to the Barry dep. Mr. Barry concluded his report with ten concrete technical recommendations for going forward with the HT project. Nowhere does he recommend any modification of the CD4Sure™ assay.

45. Both parties satisfied with the feasibility testing, PointCare immediately got to work. Mr. Bouree brought the "Feasibility Excell22" up to PointCare and installed it at the end of April 2006. He trained the PointCare HT project team[6] how to run it.

46. To save time, under my supervision, Ms. Glover started manufacturing engineering work on the way we would package and ship the CD4Sure™ assay for use on the HT. She worked on converting the AuRICA kit format that had one patient test per glass vial to a new kit that might have as many as a 30 patient test capacity per vial. She did this because the HT was to run at high speed and loading vials one by one onto the machine would slow it down.[7] Getting an immediate start on this kind of manufacturing engineering at PointCare further reinforced my growing opinion that the HT project would go quickly. Ms. Glover completed CD4Sure™ assay kit re-design and made three manufactured lots in a timely manner.

47. In late March 2006, I went to Drew and met with Mr. Bouree and Dr. Andrew Kenney, the overall Technical Director for Drew. We discussed the feasibility work that had been going on since January 2006. The three of us agreed that the HT project was feasible and we proceeded to plan a timeline for the project. After a few iterations, the timeline was agreed upon. An email from Dr. Krauledat to Mr. Rimmer dated May 9, 2006 indicates that Mr. Barry had sent the agreed upon timeline to Mr. Rimmer earlier that day. See Exhibit 4 hereto (DR624-625), a true copy of an email between Petra Krauledat and Harry Rimmer produced by Drew in discovery. She indicates that the timeline is to be part of Annex 1 to the Agreement. On May 15, 2006, Mr. Rimmer emailed Mr. Bouree asking him to check the timeline one last time. The timeline in Annex 1 of the Agreement is, to the best of my knowledge, the one that Mr. Bouree

[6] The team included Mr. Barry, Ms. Glover, Ms. Tracie Fradet, Ms. Amy Coughlin, Ms. Andrea Desrosiers, Ms. Jennifer Waite and Ms. Dorothy Branco.
[7] The assay itself would not be modified.

was asked to review in this email. See Exhibit 5 hereto (DR19458), a true copy an email produced by Drew in discovery.

48. Our experiments with Mr. Bouree from January 2006 to May 2006 showed that all the key elements that Drew would need from PointCare could be carried over from the AuRICA. By this I mean that the AuRICA CD4Sure™ assay only needed to be repackaged in a new kit, (not modified) the optical cytometer in the Exell22 could be made to work like the AuRICA optical cytometer and give good data, and the AuRICA software for CD4 counting would work to analyze this data.

49. Going forward on the HT project Dr. Kenney, Mr. BOuree, Mr. Barry and I agreed the main Drew engineering tasks would be to design, make, and test a CD4 module, turn Mr. Bouree's modified optical cytometer over to manufacturing engineering, and make PointCare's AuRICA CD4 software algorithm "talk" to the pre-existing Excell22 software.

My role In The PointCare-Drew Negotiations

50. From the first meetings in November 2005 up to the time the Agreement was signed, I attended meetings with Dr. Krauledat, Mr. Rimmer, and Mr. DePiano. Some meetings were at Drew and others were at PointCare.

51. At *no time* did Mr. DePiano, or anyone else at Drew or Escalon, ask me to "guide" Drew through the process of modifying its instrument. I never made any offer to do so. No one at Escalon/Drew ever told me that Escalon/Drew was relying on me or my colleagues to "guide" Drew. The Agreement between the parties does not include any such idea.

Drew Asserts That PointCare Agreed To Modify Its Assay To Accommodate Their Hardware

52. I had no intention of modifying the PointCare CD4Sure™ assay when we were negotiating the agreement. There was no need to do this. Mr. Bouree of Drew and I had seen the CD4Sure™ assay work without modification during our feasibility studies together.

53. Drew asserts in its brief at p. 9 that Annex 1 to the Agreement says "PointCare is responsible for making the assay compatible with the hardware." This is false and misleading. The Annex in fact says, "PointCare is responsible for and will bear the costs associated with and related to the development and approval for sale in the United States of PointCare's CD4Sure™ lymphocyte enumeration assay that will be compatible with Drew's HT diagnostic instrumentation platform." (Emphasis added) The verb "will" simply helps confirm the fact that if Drew successfully converts the Excell22 into an HT according to the plan that includes the CD4Sure assay specifications, there will be compatibility between the platform and the assay.

54. Drew further distorts the Agreement by describing Annex 1 as "the key contractual provision on the HT." Drew ignores the very first sentence of the Agreement (¶1.1), which could not be any clearer in describing Drew's responsibilities with respect to the HT: "DREW agrees to modify its current Excell 22 hematology platform to accommodate POINTCARE's proprietary CD4 Lymphocyte Enumeration Assay, CDSure." *Nowhere* does the Agreement require PointCare to "modify" its assay to accommodate Drew's instrument.

55. When the Agreement was signed, the CD4Sure™ assay was an existing, FDA cleared assay. Annex 1 does not say that PointCare will modify its existing FDA cleared assay. What PointCare will do is to prove to the FDA that the CD4Sure™ assay works on Drew's HT as well as it worked on the PointCare AuRICA, and pay for it.

56. Annex 1 to the Agreement refers to the HT and not to the Exell22. Drew had to modify the Exell22 to make the HT. The Drew HT did not exist and Drew was obliged to make it. The PointCare CD4Sure™ assay already existed and did not have to be created or modified.

I Went To Drew To Help Plan The Technical Program

57. In June, 2006, after the feasibility experiments with Mr. Bouree were complete, and just after the Agreement was signed, Mr. Barry and I attended an engineering planning meeting at Drew with respect to the instrument that later became known as the"HT". About six people from Drew were in the meeting. Dr. Andrew Kenney, Drew's Technical Director, told me that everyone needed to make technical decisions at Drew was present.

58. Dr. Kenney asked me to make the opening remarks. I described the existing AuRICA instrument and the CD4Sure™ assay. I emphasized that PointCare needed Drew to modify the Exell22 to accommodate the CD4Sure™ assay in the shortest time possible. I told the group and that a realistic timeline had been incorporated into the Agreement that PointCare was looking for a full commitment of Drew's engineering resources to the task,

59. Jerry West, a Drew senior consulting engineer, led the discussion that followed. After describing and discussing the feasibility studies that had been completed , the Drew engineers agreed that Mr. Bouree's modification to the optical cytometer could be readily turned into a manufacturable design and no further engineering development work was needed.

60. This optimism later proved to be unfounded. A year later, in the June-August 2007 timeframe, Drew HT project leader Gary Young admitted to me that the optical cytometers they were building in pilot manufacturing for the HT were unstable and unreliable. As late as November 2007, George Chappell, a senior engineer at Drew, wrote me an email looking for

advice about how to manufacture the optical cytometer which was given promptly. See Exhibit 6 hereto (DR44928), a true copy of an email between George Chappel, Don Barry and me.

61. The next discussion took longer. Mr. Barry and I described the steps of the PointCare CD4Sure™ assay. Someone from Drew listed the steps on the white board as we spoke. Mr. Barry and I answered questions from the Drew engineers. We told the Drew engineers that the PointCare AuRICA already automatically performed the CD4Sure™ assay and showed them how it worked. We said there were approximately 65 AuRICAs in the field and they worked. We were not looking for new technology from Drew; a repeat of the AuRICA would be fine. I knew that an existing Drew instrument (called the D3) had computer driven needle and syringe technology similar to the AuRICA. I suggested they could use that existing technology to perform the CD4Sure™ assay in the HT.

62. The Drew engineers rejected the existing AuRICA and D3 method of performing the CD4Sure™ assay at this meeting. They sketched out a different design on the white board. It became known as the "CD4 Module."

63. During the discussion of the CD4 module, Mr. Barry and I pointed out that the CD4Sure assay used some chemicals that should be checked for compatibility with any materials Drew might use in its new CD4 Module. We pointed out that the CD4Sure assay contained a very strong acid and very strong base that could corrode parts of the CD4 Module and other parts of the machine. We also alerted Drew that the immunogold in the CD4Sure assay stuck to some materials and not others. See Exhibit 7 hereto (DR74904), a true copy of Sample Prep.

64. According to the Drew engineers, the new CD4 Module would carry out each of the chemical steps of the CD4Sure assay. It would have suitable pumps, valves, mixers, tubing, and a heater.

65. Dr. Kenney and the other Drew engineers assured me that they had prior experience in all components Drew needed to build the CD4 Module (pumps, valves, mixers, tubing, and heater). They stressed that since this was all familiar to them, they could build their idea more quickly. As Drew had ultimate responsibility for modifying its Excell22, PointCare deferred to Drew's decision to use the Drew CD4 Module design concept (instead of proven, pre-existing technology).

66. One specific part of the proposed CD4 module was new to me and I asked for an explanation. The Drew engineers told me it was an optical sensor connected to a very small pump. The sensor-pump combination would measure the right amount of the CD4Sure™ immunogold reagent (the PointCare proprietary chemical that was the "heart" of the CD4Sure™ assay). The Drew engineers told me they already used optical sensor-pump combinations on equipment they currently manufactured, and that they worked well. The new ones for the HT would work the same way, but they would be smaller because the amount of immunogold to be measured out was smaller. They were confident it would work.[8]

67. Mr. Barry expressed concern that the immunogold would coat the optical sensor on the pump, forming an opaque layer and blocking light. If enough light was blocked, the sensor would not work.

[8] In fact Drew's optical sensor-pump approach never worked. Drew finally switched to an ultrasonic sensor on the pump in mid-2007.

68. Several people suggested materials that might not become coated. Mr. Barry suggested that the material needed to be smooth. He cautioned Drew about "machining"[9] these surfaces.

69. Drew alleges that PointCare is at fault for not warning Drew that the immunogold in PointCare's assay might adhere to the optical sensor Drew decided to develop for the HT. This is not true. In the meeting on June 13, 2006, with all relevant Drew engineers present, Mr. Barry told the group that the PointCare immunogold would stick to certain materials See Exhibit 8 hereto (DR6730), a true copy of a memo between Andrew Kenny and Karl Gu

70. Drew accuses PointCare of failing to solve the immunogold sticking problem for Drew. This assertion ignores that Drew, not PointCare, suggested the sensor-pump combination and it was Drew's responsibility to modify the Excell22 to accommodate the PointCare CD4Sure assay.

71. In good faith, PointCare suggested alternatives to the sensor-pump combination at the June 13, 2006 meeting.

72. First, PointCare suggested that Drew use the AuRICA method for dispensing immunogold. The PointCare AuRICA did not need optical sensors combined with pumps to measure out immunogold. The PointCare AuRICA used a computer-controlled syringe and needle to meter out immunogold. This method was reliable and proven in the field on about 65 AuRICAs. Drew rejected the AuRICA method. PointCare cannot be later blamed for the consequences of Drew's rejecting PointCare's proven method.

[9] "Machining is a term of art in mechanical engineering. It denotes making shaped parts by the use of "machine tools" such as lathes and drill presses. To make a "machined part" one starts with a block of plastic or metal and grinds or cuts it into shape. This process always leaves scratches that later must be removed.

73. Second, PointCare suggested using the method of Drew's own D3 instrument. This method was very similar to the AuRICA and therefore had a high probability of success. Drew rejected this method as well.

74. We offered our ideas in good faith. They were technically sound and we had first-hand knowledge about them. Drew, not PointCare. delayed the project by rejecting these ideas.

75. It was never an option for the HT to use something other than the CD4Sure™ immunogold. PointCare had fine tuned this reagent to stick specifically to CD4 cells. Modifying its "stickiness" so it would not coat a Drew optical sensor and still stick to CD4 cells was never suggested. If it had been, I would have rejected it.

Software Planning

76. At the end of the meeting at Drew in June 2006, Karl Gu (the Drew software development manager) objected to Drew sharing its secret source code with PointCare and that meant he would have to manage the PointCare staff for HT software. He said that he was very busy and did not have enough time for this. He was very firm and very vocal.

77. In the discussion that followed, I learned that Mr. Gu worked from home a lot (two days a week) and that Mr. Gu was the only person at Drew working on system software. I learned that an outside consulting firm provided assistance to Mr. Gu from time to time, but they were not available for the project. This was not good news.

78. It was clear that Drew was understaffed in software. I asked that the outside consultants be made available for the project. Mr. Gu agreed to discuss this with Mr. Rimmer, Drew's President.

79. I said PointCare would help by assigning three software engineers to the HT project, but for a limited time. I explained that PointCare's other project (the NP) would need all of PointCare's software attention in early 2007.

80. I agreed to having Mr. Gu manage the HT software development. I did so, in part, because he said Drew must keep their Excell22 software secret. This important condition put on the project by Mr. Gu meant that only he would know how to make any PointCare software communicate properly with the HT. He confirmed that only he would be capable of "software integration" for the HT project. I agreed with him. Drew produced an internal planning document for this litigation where Mr. Gu is clearly identified as the person responsible for software integration. See Exhibit 8 hereto.

81. I discussed that the feasibility study had shown that the old AuRICA software (CD4 algorithm) worked on the data coming out of the modified Excell22. Mr. Gu would just have to show PointCare how to make this AuRICA program communicate with his "secret software." He said that he would use a method called creating a "dynamically linked library" (or "dll") to allow him to move the old AuRICA CD4 software to the HT. He said he would create the "CD4 dll." The CD4 dll (pronounced "dee, ell, ell") would integrate the PointCare CD4 software (CD4 algorithm) into the HT[10]. I deferred to Mr. Gu's apparent expertise with "dll's".

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[10] Algorithms are math instructions to a computer. "Take this number, multiply it by two, and store the answer here" is a perfectly good algorithm. Computers use "languages" to "run" the algorithm. If the language can get directly to the algorithm and make it run, then the algorithm is said to be an "executable" algorithm.

One very common computer language used to execute algorithms is called "Visual Basic." PointCare's first CD4 instrument (AuRICA) used Visual Basic to directly execute its algorithms.

Some algorithms are so useful that computer scientists like to carry them from one product to another product where the language in the new product may be different from the original product. One of the algorithms that PointCare developed for its first CD4 counting instrument was called the "CD4 algorithm", and it was very advanced and useful for new products to count CD4 cells.

Time Is Of The Essence

82. I asked Mr. Gu to come to PointCare to meet the PointCare software group, see a demonstration of the software they had developed for the AuRICA, and organize the tasks.

83. During the meeting, I emphasized to Drew's engineering team that time to product launch was of the essence and part of the contract between Drew and PointCare.

84. At no time did anyone in the room refer to the timeline for product release as a "guideline" for product release. I made it clear to everyone that the timeline was a firm, contractual commitment.

Mr. Gu Is Late To Organize The Software And is Under-Resourced When The Project Starts

85. I have first-hand knowledge that Mr. Gu waited a full month after the technical planning meeting to have his first meeting with his PointCare software engineers and even tell them what he wanted them to do. The document (See Exhibit 9 hereto (DR 19877-19887), a true copy of PointCare Technical Review Meeting) produced by Drew in this litigation is the minutes of this belated meeting which show that Mr. Gu is the HT software project manager and late to start. See Exhibit 10 hereto, a true copy of PointCare Supp. 10036, an email exchange where Mr. Gu accepts the minutes.

To allow the PointCare CD4 algorithm to be carried to a new product that does not execute the algorithm directly in Visual Basic, a computer scientist must first "wrap" the algorithm in a new small program called a "wrapper." The wrapper allows the algorithm to safely communicate with the software language in the next product. Sometimes this language is not "off the shelf" like Visual Basic, in which case "source code" is needed to in order to know how to talk to it.

Two computer programs rarely get along. Typically they refuse to talk or they fight. A properly designed wrapper prevents this. It makes a friendly communication link inside the new product; it protects the algorithm from damage , and vice versa.

The whole package (algorithm plus wrapper) is called a "dynamically linked library" or "dll." The value proposition for any dll is that the wrapper is necessary for good relations with the new product , but the algorithm is the crown jewel.

86. Mr. Gu had committed to me that he would be responsible for software integration. I learned from documents produced by Drew for this litigation that he is listed as being responsible for software integration (see Exhibit 8 hereto) and later, on another document. See Exhibit 11 hereto (DR22216-22219), a true copy of CD4 Customer Software Project Status Meeting, listing Drew's outside consultant Jason R. Werner (JRW), under Section 2 "Integration", as responsible for the integration portions of the software project. The document also specifically states that "JRW will be [sic] assist with any problems or questions related to the integration of the dll."

87. I found out in documents produced by Drew for this litigation that a week after the July 13 organizational meeting, Mr. Gu emailed to his boss Dr. Kenney saying that he felt strongly that more resources were needed for the HT project. See Exhibit 12 hereto (DR19860), a true copy of an email between Andrew Kenny an Karl Gu. In other words, Mr. Gu was still looking to his management for resources one month after the big June 13 technical planning meeting, when he made clear that the HT would need more software resources.

88. Three months after the meeting, Mr. Gu delivered a CD4 dll to PointCare. See Exhibit 13 hereto (DR21112-21114), an email between Karl Gu and Andrea Desrosiers. Mr. Gu did not put the PointCare CD4 algorithm inside the CD4 dll he delivered. He made up something on his own that was too simple for the job. See Exhibit 14 hereto (DR21299), an email between Karl Gu and Andrea Desrosiers. He told PointCare to replace his CD4 algorithm with the AuRICA CD4 algorithm.

89. There followed months of Mr. Gu and the PointCare group trying to get the PointCare CD4 algorithm into Mr. Gu's CD4 dll, and then have the dll communicate with the

HT. PointCare was handicapped during this process because it did not have the Drew secret source code.

90. I intervened and spoke to Drew's outside software consultant in February 2007. Sometime in March 2007 the communication worked, after help came from Drew's outside consultants. The consultants knew the Drew secret source code.

91. In March 2007, Drew had yet to develop a working HT engineering prototype that could put out data that the CD4 dll could recognize.

92. No purpose would have been served by integrating the dll into a Drew prototype that was incapable of outputting data that the dll could recognize. The CD4 dll work did not delay the HT prototype.

93. From March to June 2007 PointCare shouldered the task of finding out why the Drew engineering prototype did not work. In June, Mr. Young and I agreed that Pointcare had found the problems and now Drew would fix them. PointCare sent the CD4dll to Drew in June, in case they got the HT engineering prototype to work, they would have this CD4dll to integrate into the working system.

94. I have no evidence that Mr. Gu ever tested or used the CD4 dll after it was delivered.

The Drew Engineers Were Late To Get Started On The Hardware

95. In the field of technical product development, an "engineering prototype" is a system that performs the key functions of the final intended product, but it does not look like the final product. I expected Drew would provide PointCare with an engineering prototype of the HT ready for in-house testing in the August-September timeframe, as required by the

Agreement (Attachment 1 to Annex 1 of the Agreement line 32) Drew did not meet this expectation.

96. In August 2006, instead of delivering an HT engineering prototype, Drew delivered a new part for the old "feasibility study" Excell22. The new part was another modified optical cytometer.

The Drew Engineers Cannot Get Good "Dot Plots" From Their Engineering Prototype

97. By December, 2006, Drew engineers had not been able to get acceptable dot plots[11] on a consistent basis with the engineering prototype. I sent Amy Coughlin, a PointCare R&D employee familiar with the "feasibility Exell22" at PointCare, and experienced in judging dot plots, down to Drew to helpin January to March 2007. I did this as a good faith gesture even though her help was not required by the Agreement.

98. She reported back that the data produced by the automated engineering prototype at Drew were usually unrecognizable (the dot plots were bad) and could not be analyzed by any software. Occasionally they were good for one or two runs, but then went bad again. If she ran the prototype using the manual CD4Sure assay. (instead of the automated assay), the data were consistent, recognizable and of good quality (good dot plots). So the assay was not the cause of bad dot plots and the optical cytometer worked. There was no CD4 dll in the machine and there was no user interface software in the machine. So software was not at fault. I concluded the new Drew CD4 module was at fault. Mr. Young and Mr. Chappell agreed with me.

[11] Dot plot" is a term of art in the industry. It is a visual way to display the data coming out of an optical cytometer. Each cell that goes through the optical cytometer creates an electronic signal that makes a dot on a computer screen. More dots are made as more cells go through the optical cytometer. If everything is working right, the dots tend to group in distinct clusters on the screen with no overlap. Each cluster is a cell type, and each dot in a cluster is a cell of that type. When the instrument works properly, it generates crisp, distinct clusters that can be recognized and analyzed by a computer. The PointCare CD4 algorithm figures out which cluster of dots are CD4 cells and then counts the dots in the cluster.

99. From January 2007 to March 2007, between Mr. Barry and Ms. Coughlin, PointCare had someone almost continuously at Drew, at PointCare's expense, trying to assist Drew with fixing the engineering prototype so it would consistently give good dot plots.

100. I sent PointCare people to Drew to collaborate and to help. Drew did not reciprocate. This email from Gary Young to his boss Andrew Kenney sent on November 8, 2006, see Exhibit 15 hereto (DR21441), an email between Gary Young and Andrew Kenney, illustrates Drew's non-collaborative attitude and management style:

> Andrew, Don is proposing sending Ami Kaufman Amy Coughlin], Field Engineer, down the week of the 27th to oversee progress and assist. Her stay would be "for as long as we need her." He is sending her in his place because his schedule is full in December. I think it would be a good idea. If we use her only minimally, it may calm PointCare enough to get them to back off. I sense they are very jittery at the moment. So much is being said by [Drew's] Frank [Matuszak] to PointCare and by Frank to [Drew's] Doug [Nickols] that I don't feel we are getting the whole story. In other words, POLITICS!

101. I was indeed jittery, but I did not send Ms. Coughlin down to "oversee" or manage the project. She went to Drew to help. One way was to help the engineers understand CD4 dot plots. I was also "jittery" because no one at Drew could tell me if any particular part of the CD4 module was at fault.

102. I went to Drew in the first week of March 2007 to see for myself what was going on. I saw that the dot plots were inconsistent: sometimes good, but mostly bad. I could see for myself that Drew had made little progress. We were actually past the point where we should have launched the HT as a product according to the timeline in the Agreement.

103. During my trip to Drew, I spoke with Drew's Gary Young. Drew's George Chappell who designed the CD4 Module and the nor anyone else at Drew could tell me why Drew's engineering prototype CD4 module did not work consistently. No one at Drew had an idea of how to fix it. I could, however, see that part of the problem was that Drew lacked the

tools to troubleshoot the CD4 module. For example, they had no biological microscope. When troubleshooting blood cell counting prototypes, engineers will stop the machine and take out a small sample of blood to see if the machine has done the right thing to the blood. They look at the sample with a specialized, high power, biological microscope with so-called "oil immersion" optics. These microscopes cannot be used for other purposes, and are kept in the engineering development lab. Before going to Drew, I have never experienced a company making blood cell testing equipment that had no microscope for looking at blood cells.

104. I suggested to Dr. Kenney Mr. Young, Mr. Chappell and Mr. Nickols that we take one of Drew's three engineering prototypes up to PointCare where we had troubleshooting tools, and that one of the Drew engineers come along. We would see if, with better tools, we could get to the bottom of the CD4 module problems. I did so in a good faith effort to assist Drew.

105. I asked Mr. Chappell to come along but he said that family matters prevented this. Mr. Nickols refused to send another engineer, saying they were too busy with other matters. To my knowledge, no one at Drew ever objected to my idea of sending one of the machines to PointCare. Drew packed the machine a few days later (in approximately the second week of March 2006) and shipped it to PointCare.

The HT Engineering Prototype Comes To PointCare For Troubleshooting

106. In March 2007, Drew delivered an HT prototype to PointCare for troubleshooting. By March 20, 2007, using PointCare's better diagnostic methods, Ms. Coughlin reported to Drew that she was now able to get good dot plots (computer-recognizable data) from the prototype. See Exhibit 16 hereto, Exhibit 5 of Barry Dep.

107. Ms. Coughlin further reported to me that she could only get these good dot plots for a short time and showed me her data. She continued her troubleshooting and traced this

significant reliability problem to the optical sensor that Drew installed on the CD4 module pump. The sensor had to be able to "see" inside a tube coming out of a miniature pump and tell the pump when to turn on and turn off. She saw that this tube became coated with CD4Sure™ immunogold. Once coated, the sensor could not detect light and the CD4 module stopped working.

108. I reported this problem to Dr. Kenney at Drew on March 16, 2007. I gave him some suggestions for tubing materials that might help. Most importantly, I repeated what I had said in the June 13, 2006 meeting, which was that the inner surface of the tube must be smooth or "polished" (which can be achieved by molding the tube, not by maching them). See Exhibit 17 hereto (DR23642-23643), a true copy of an email between me and Andrew Kenney . I told Mr. Young that Drew should fee up the money and mold this part.

109. The Drew engineers subsequently refused to consider any material that needed to be molded (such as polyethylene or polypropylene). They wanted to make the plastic parts using cutting machines in their own machine shop. They said it was quicker to do this and cost less. I have first-hand knowledge that polyethylene and polypropylene could not be shaped this way. Random scratches cannot be avoided in a machine shop cutting process with these plastics. Immunogold as well as other chemicals that normally do not stick to them get trapped in the scratches. Mr. Barry and I told this to Dr. Kenney, Mr. Young and Mr. Chappell.

110. Drew asserts that PointCare misled them with its suggestions. Nothing could be further from the truth. We made the suggestions in good faith. We consulted with others on Drew's ideas of machining soft plastics materials into the right shape. No one could figure out how to do it. Many people advised molding as we had suggested.

111. I repeatedly looked for suggestions so Drew could overcome the problem of immunogold stickies not to Drew's optical sensor. In a March-April 2007 time frame, I asked Don Barry to think of ways Drew could avoid using an optical sensor with the Drew pump. Mr. Barry came back to me in about a week and suggested using an ultrasonic sensor. Immunogold coating would not affect an ultrasonic sensor. The idea sounded good and I told him to call Mr. Young to pass the idea along, and he reported to me that he did so. In late July or early August, Mr. Young told me in a telephone conversation, that Drew was going to try the ultrasound option. I communicated this conversation to Mr. DePiano because I could no longer locate Dr. Kenney or any replacement technical Director at Drew. See Exhibit 18 hereto (DR1489), a true copy of an email between me, Richard DePiano, Doug Nickols and Frank Matuszak,

112. In its brief, Drew blames PointCare for Drew's failure to make a CD4 module because PointCare supposedly misled Drew engineers on how to solve the immunogold coating problem. This is a distortion of the facts. The CD4 module must accurately "meter" a tiny drop of immunogold into a mixing chamber. There are several ways to do this. In the group planning meeting in early 2006, Drew engineers picked the optical sensor method because they said it was familiar to them.

113. Another way for the instrument to meter immunogold into a mixing chamber is the PointCare AuRICA method. AuRICA used an electronically controlled, precision syringe and a needle to meter this drop into a mixing chamber with an accurate volume over and over again. Drew was well aware of how the AuRICA worked but rejected the idea at the June 13, 2006 meeting.

114. In contrast, PointCare's other development partner C2 Diagnostics ("C2") successfully used the AuRICA computer driven needle and syringe method on the NP machine and substantially met its product development timeline.

115. During her troubleshooting in or about April, May, Ms. Coughlin began to isolate another, significant problem in the HT engineering prototype. She told me that the optical cytometer did not remain stable over the course of the day. As a result, the dot plots for the same blood sample changed over the course of the day. I joined her for some work on this, and saw the change for myself.

116. In response to my request, in June, 2007 Drew sent a technician to PointCare (for the first time since Mr. Bouree in April 2006) to look into the optical cytometer stability problem. The technician, Mr. Tuan, said that some of the optical cytometers that Drew had sent PointCare were defective. He left some good ones behind and went back to Drew. Despite repeated requests, I could never get a report from Mr. Tuan as to what he had found.

117. In a late July-early August 2007 telephone conversation with Mr. Young, he told me that Mr. Chappell had diagnosed the optical cytometer problem as an electrical short circuit. (Exhibit 18 hereto). Drew apparently had not solved the problem by November when Mr. Chappell wrote to asking for advice on the still unstable optical cytometer. See Exhibit 6 hereto (DR44928).

The Engineering Prototype Goes Back To Drew To Redesign The CD4 Module And The Optical Cytometer

118. In May 2007, Mr. Barry and I concluded that the HT engineering prototype would need significant redesign at Drew. He and I insisted that Drew hold telephone meetings with us to create a plan of action. See Exhibit 20 hereto (DR1395, DR27708-27709), an email to Don Barry and an e-mail between Peter Hansen and Gary Young. That plan culminated in the visit by

Mr. Tuan and the joint decision to send the HT engineering prototype back to Drew for redesign, which we did in June.

119. I was copied on emails that Mr. Barry sent to Mr. Young during the period from June 6 to June 26, 2007 asking for updates and Mr. Young responded with superficial and unhelpful information. See Exhibit 21 hereto (DR27981, DR27992-27995), a true copy of emails between Don Barry and Gary Young.

120. I telephoned Mr. Young near the first part of August. He gave me a telephone update of Drew's work on the returned HT engineering prototype. I summarized the call in an email to Mr. DePiano, Mr. Matuszak, Mr. Nickols, Dr. Krauledat, and Mr. Barry. Exhibit 20 (DR1489).

121. In that same email I noted that we had shipped more immunogold to Drew for their work on the HT. We never charged Drew for these expensive reagents.

122. On September 13, 2007, I phoned Mr. Young and sent him an email requesting an update on Drew's progress.

123. On September 18, 2007, Mr. Young emailed me (confirming an earlier conversation) that all of the HT prototype problems had been resolved and he would ship the instrument back to PointCare on September 18, 2007. See Exhibit 22 hereto (DR1385-1386), a true copy of an email between Peter Hansen and Gary Young.[12] Unfortunately, Drew found new problems and the promised shipment never happened.

[12] In footnote 8 of its Brief, Drew cites PointCare board meeting minutes held on September 13, 2007, where it is reported that the HT is working after the resolution of the remaining technical issues. In my deposition, I disputed the accuracy of these Board meeting minutes. I was mistaken. Reviewing Exhibit 22 in this case refreshed my memory.

There Is No Technical Director At Drew So I Ask For A Upper Management Review At Drew

124. In early July 2007, I grew increasingly frustrated by not getting concrete information from Drew. I went over everyone at Drew's head conveyed my concerns by an email to Escalon CEO Richard DePiano, Sr. See Exhibit 23 hereto (Exhibit 1 DePiano Affidavit).

125. Escalon's General Counsel replied. See Exhibit 24 hereto (DR14-16), a true copy of an email between me and Richard J. DePiano, Jr. His letter continues several distortions and outright falsehoods.

126. He said that I had complained that I was unable to get communications from Drew relative to project timelines and status. This was true.

127. He said that I had demanded that Drew send us two HT engineering prototypes even though Drew was reluctant to do so. This is false. I never demanded anything. I made a suggestion. No one at Drew disagreed with me. Drew, not I put the machine in a shipping crate and shipped it to PointCare.

128. He said that Drew's engineers would not be readily available to assist if the engineering prototype was at PointCare. This is false. PointCare technical staff was at Drew for approximately two months to help Drew. It was equally possible for Drew to reciprocate.

129. He said that the HT machines were fully operational (less the PointCare assay mixing) when Drew shipped them to PointCare. This is false. The optical sensors in the CD4 module did not work and the optical cytometer did not work.

130. He said that without consulting Drew, and against specific instruction PointCare unilaterally disassembled the prototypes when they arrived so PointCare could work on the "Assay Mixture Component" development, and, in so doing, we damaged and misaligned key

components of the equipment. This is false. We worked on finding out why the machine did not work. All of this work was done under Drew's supervision by telephone and email. Ms. Coughlin, our engineer on the project, had completed the Drew Field Service Engineer course and was certified by Drew to disassemble and adjust the equipment.

131. The general counsel appears to have not understood my email or the information he got at Drew. He says that, "While you are correct that PointCare's assay appeared to work in a preliminary trial, you fail to mention that the automated mixing method was built per specifications provided by PointCare." This is false. Had it been built to our specifications, it would have worked.

132. He goes on to say that Drew "was able to effectuate an appropriate modification" of the optical sensor to eliminate the gold sticking problem. This is false. At the time of the general counsel's letter, no one had effectuated an appropriate modification. It was two months later that Drew said that it reached a solution to the problem by dropping optical sensors altogether.

133. He says again that Drew met its obligation and shipped two (2) operational AuRica HT instruments to PointCare. This is false. No instruments ever shipped to PointCare by Drew were ever fully operational.

134. He says that PointCare provided Drew with major "change orders" for the engineering prototypes. This is false. PointCare never issued a "change order" to Drew for anything.

135. He ends by saying that he expects PointCare to promptly proceed with clinical studies. This statement reveals his unfamiliarity with the subject matter. In November 2007, five months after the General Counsel's letter, Drew hired an independent consultant, Dr.

Herbert Chow, to test the status of the HT prototype. See Exhibit 25 hereto, Exhibit U to DePiano Affidavit. When Mr. Chow testified about his work in his deposition he said that the prototype was not ready for pre-clinical studies let alone clinical studies. See Exhibit 26 hereto, Chow Tr. 145:14-16.

136. General counsel's letter contained so many distortions and falsehoods that it heavily strained the collaborative nature of the project. Given that PointCare did not have a working HIT prototype from Drew needed for forther work on that project and the pressing demands of the NP project, I allocated PointCare personnel accordingly. Contrary to Drew's accusations, I did not instruct my personnel to abandon the HT project. To the contrary, I encouraged them to provise assistance to the best of their abilities.[13]

137. After receiving general counsel's letter, we continued to support Drew's efforts with regular reagent shipments free of charge and reviewing data when asked. In fact, one of Drew's engineers asked for a data review in November, weeks after PointCare gave its notice of material breach to Drew. PointCare performed this review promptly.

138. Without a working HT prototype from Drew, and having returned the non working HT prototype to Drew for re-design, see par 118 above, there was not much more that we could do on the HT until Drew solved the problems and sent us a working prototype.

139. The way-off schedule HT project was now causing resource problems at PointCare. The release date for the NP was just three to four months away and this was "crunch time." PointCare needed a product to sell; and we needed to fulfill our contractual obligation to

[13] On Thursday, June 28 Derw makes much of an email I sent to Don Barry suggesting that we "not have anymore email exchanges" with Drew until I was able to meet with him that Monday, June 28 to dismiss the pressing issues of Drew's delays and NP timetable crunch. My sole intent was to leave Mr. Barry undisturbed for a short period of a few days during which he was in a servere time crunch.

Drew with regard to having developed an NP product. This resource conflict never would have occurred if Drew had adhered to the HT development timetable in theAgreement.

140. On December 7, 2007, Richard DePiano notified PointCare that its expert Dr. Herbert Chow had "validated" the operation of the HT prototype, and the instrument was ready to be delivered to PointCare. (DePiano Aff. Exh M). I asked Drew to provide us with the underlying test data supporting Dr .Chow's conclusion, so that I could determine whether the instrument indeed was ready to proceed to next steps. (Id. Exh. N.) I wanted to avoid shipping and doing validation procedures on a non-working instrument for a second time. Drew refused.

My Participation In Merger Discussions With Drew And What I Learned

141. During the March to May 2007 period, I participated in meetings with Drew and Escalon management concerning a possible business merger between PointCare and Drew. In these merger meetings, Mr. DePiano told me that he considered the Drew technical staff to be incompetent and they had never met a timeline. In other merger meetings, Mr. Doug Nickols, the acting President of Drew (replacing Mr. Rimmer) said to me that he would like to fire the entire Drew engineering staff. Mr. DePiano said to me that if the merger went through, he would like me to run the Drew technical programs. He also said that he was actively trying to get Andrew Kenney to accept a severance offer.

142. I knew that the HT project was way off its timeline at Drew but I thought the engineers were more competent than Mr. DePiano and Mr. Nickols thought. My analysis for Drew's engineering failures was that the engineers had no competent management. Dr. Kenney had spent most of his time in England working on another Drew project and was only occasionally at the Drew Dallas facility. He was hard to contact. I always had difficulty reaching him for decisions on the HT. Dr. Kenney simply disappeared from the HT project

sometime in the summer of 2007 and Drew did not replace him. Things then went from bad to worse. I had no one to contact at Drew about HT management issues other than Gary Young, and he had little or no authority.

Conclusions

143. I went into the HT project with high hopes and enthusiasm. I saw the HT as an important product for 40 million sick people in the world.

144. I instructed my staff at PointCare to share everything they could in the way of knowledge and resources to help Drew with the HT. To the best of my knowledge, they did just that. Drew never reciprocated. Mr. Gu refused to share software code with full knowledge that this would mean more work and a longer timeline. Mr. Tuan refused to share his findings when he told me that some optical cytometers they were building were defective right off the production line and could not be expected to produce good dot plots. Drew blamed us for these failures, saying we had taken the optical cytometers apart without their permission and that's why they did not work. Drew refused to take our advice and mold the plastic parts for the CD4 module optical sensors. They then blamed us when they "machined" the covers and found the scratches caught immunogold and then failed. Collegiality left the project when Escalon had its General Counsel write to me a letter full of distortions and falsehoods and directing me to get on with my responsibilities and run a clinical study. Had I followed these orders, the non-working HT prototype would have been on display for the world to see, and everyone would have been harmed. Had I followed these orders, I would have gone directly against Drew's consultant Dr. Chow, who said at deposition that the HT prototype in December 2007 (well after Escalon had its General Counsel's July 2007 letter) was not even ready for a small pre-clinical study, to say nothing of a full scale clinical study.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 25th day of April, 2008, in Boston, Massachusetts.

W. Peter Hansen, Ph. D.

EXHIBIT 1

Test report
Date: January 05, 2006
Topic: testing of CD4 detection using Point Care Technologies Gold method
Participants:
DREW Scientific: roger Bourrée
Point Care Technologies: W. Peter Hansen, Chief Scientific Officer
Donald E. Barry, Scientist

Foreground: Point Care technologies has developed a method for the tagging of CD4 lymphocytes using gold particles that can be used on flow cytometers operating in the visible range (cheaper) instead of fluorescence.
CD4 counts are a vital tool in monitoring HIV.
Point Care Technologies currently sell a tabletop flow cytometer based on the IDDEX animal 5 part differential. This system is slow and Point Care Technologies does not seem too happy in their relation with IDDEX.

There are two main topics in our discussions with Point Care Technologies:

1. Can we design for them a substitution to the IDDEX machine using the EXCELL 22 optical head as a base?
2. Can we adapt their technology to work on the EXCELL22 (in fact 2280) that will greatly enhance the EXCELL 22 appeal (there is no other machine in that class that can run CD4)

The purpose of this work was a first evaluation of the possibility to read CD4 on the EXCELL 22 optic bench without modification (if possible).

Point Care Methodology as used so far

50 µl of whole blood
+ 20 µl of CD4 Immuno Gold
+ 5 µl of accelarator
VORTEX for 5 sec

Incubation (variable)

+ 300 µl of Lysing reagent
VORTEX for 8 sec

+ 135 µl of quench reagent
VORTEX for 10 sec

Make up with volume and analyze.

Most of the time the analysis was done by pouring the blood/gold mixture in the WOC cuvette and using a Presample (dilution) Deck where the sheath dispense had been disabled.

Testing:
In all cases the run were performed with XL 22 UTILITY rather than the User Interface, this solution gave us a better view of scattergram details and provided a direct flow access to the flow rate graph.
A total of 18 tests were recorded (we run out of CD4 gold marker)
8 tests were performed with the optics in standard configuration but with sheath dispense disabled
2 were performed by replacing the lysing step in Point Care technologies protocol by DREW sheath and no Quench, the dilution was performed by the analyzer.
8 tests were performed after removing the side mask on the flow cell. First with standard gains, then with increased gains and finally with increased laser power and normal gains.

Results:
Overall we can observe the presence of two Lymphocyte populations when the CD4 marker is added (this is what we were looking for). These two populations are more or less differentiated depending upon incubation, mixing and gains/laser power combination.
Our existing software tool (UTILITY) could sometime cloud the visual aspect of things because populations with CD4 did no behave like in the standard XL22 operation but when the data file (fcs) were opened with a specialized tool (FCS express) the presence of the CD4 population was easy to verify.
There was also a lot a variables introduced by the fact that the pipetting and mixing were mostly manual and as such not fully reproducible from sample to sample.

Where to go from there:
Our partners at Point Care technologies are very exited by the results and wish to go with further experiments.
I sent them a cube of our sheath and a bottle of our Lyse for protocol adaptation at their place.
Point Care technologies want to come back down here before the end of the month to work further on the instrument, in order to make that time worthwhile several things would help:

1. Prepare a simplified dilution sequence with a reduced flow cytometer inj line sample size and some customizable incubation time – this I can do myself (about half a day).
2. If possible, modify a UTILITY software in order to collect data (fcs file) on more than our current limit 10,000 events. For this Karl Gu participation is needed, Karl shall give me an estimate of the task complexity shortly.
3. While they are here I do not need to be involved full time as they will run multiple experiments in the same configuration.

This is definitively an interesting possibility for a product enhancement and the next experimental step should tell us what we could really expect in term of work to make this a salable feature.

Roger Bourrée

EXHIBIT 2

From: Harry Rimmer
Sent: 2/12/2006 6:14:59 PM
To: Roger Bourre (remote)
CC:
Subject: RE: Point Care Technologies

Roger, thank you for the reports on Trilogy, D3 and poiintcare. Lets talk early next week to explore timing and resources.
Harry

From: Roger Bourree [mailto:rbourre@attglobal.net]
Sent: Saturday, February 11, 2006 6:08 PM
To: Harry Rimmer
Subject: Point Care Technologies

Harry
Peter Hansen and Don Barry spent 3 days this week in Dallas as a follow up of their January visit. The main purpose was to confirm January encouraging results and also to test mechanical mixing as provided by the EXCELL22 as well as to evaluate the possibility to use DREW sheath as lysing reagent instead of Point Care lysing reagent.
We also used that opportunity to test a DREW experimental optic head with less stray light than the standard production optic head.
In most cases dilutions were prepared manually and only the mixing and analysis were performed by the EXCELL 22 (same unit as the one used in January)

Results:

Optic: DREW experimental optic head gave us the best results compared to the standard head. We need to keep in mind that our PMT not in the optimal position (on DREW optic head, the PMT is set to read scatter at 45 degree instead of the optimum 90 degree recommended by PointCare Technologies for CD4 testing).

It would be very easy to modify DREW optic head to read both 45 and 90 degree.

Mechanical mixing: in the CD4 application, DREW current paddle mixing is not as efficient as the VORTEX mixing used by PointCare Technologies. There are other paddle designs that may do the job. We also discussed some fluidics configuration that may work as well.
Lysing: in this application, PointCare Technologies reagent does a better job but DREW sheath is better at keeping non lymph populations intact. If we give this project a go, we will have to work with their Lyse.
Software: none of our current software is really good at separating CD4 Lymph from non CD4 Lymph. this is no surprise but I think that this is not out of reach for our software engineer.

Moving forward:
Peter Hansen seems convinced that a commercial product can be made available in one year time!
Challenges ahead:

Sample preparation: PointCare protocol is based on small sample and reagent volumes that are not the best suited to the shear valve dilution technology used by the EXCELL 22. We have to keep also in mind that PointCare Technologies want to use the Autosampler (critical due to the nature of the samples).

I had lengthy discussions with Peter on that topic and while a clean solution still has to emerge, we have several avenues to explore. Most likely we will have to design a dedicated CD4 dilution module that integrates in a compact package all the dilution steps required (incl mixing).
More brain storming is needed, we need to bring others into the discussion..

Optics: our optic head can easily be fitted with two PMT (45 ° as required by our patent - 90 ° for CD4). For validation of the concept, modifying one prototype head will probably cost only 2 hrs of our machine shop time and one PMT (~ $ 450). We don't even have to modify the electronics as one of the existing channels (SA) could be used (Ext and SA are redundant).

The best results with CD4 were obtained with an increase in Laser power, we will have to verify the impact of that added power to the EXCELL 22 differential results (comparison on at least 200 patient samples with the standard and increased power).

Software: as usual this could be the bottleneck

There are two different operating modes to be considered for an EXCELL22 with built in CD4 testing

The CD4 run is integrated into a CBC run.
The CD4 run is a separate process that borrows some data from a regular CBC run (Lymph total count. Hgb..)

I personally favor the second approach as more flexible and with less risk of damaging the existing software structure.

Early next week, Peter will send me the results from the data collected this week after processing through their research software. The tool that I have here is too primitive for good analysis.

PointCare says that they are willing to assign at least 4 persons to the project (this includes two software engineers).

This is definitely a project worth doing as this parameter is only offered on top of the line

hematology analyzers (> 100K) or dedicated flow cytometers.

Roger Bourrée

EXHIBIT 3

From: Peter Hansen
To: Roger Bourree; rbourree@MWI-DANAM.COM
Subject: Don's Report
Date: 4/5/2006 6:27:51 PM

Attachment N1: HT-0001 System Mod Feasibility.doc

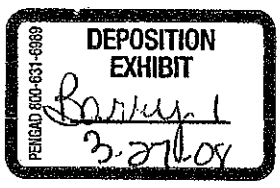
Title of Project: High Throughput System for Developing World Market

Date: March 27, 2006

Author: Don Barry

Approvals:

APPROVALS				
name	Signature	date	Title	Document Approval Function
Don Barry			Scientist/Engineer	Originator/Project Manager
Romiya Glover			Scientist	Technical Review
Maurice Doire			Director, QA/QC	QA/QC



Abstract

The Excell 22 (Drew Scientific) has been identified as an instrument that can be adapted to accommodate a CD4 immunogold assay. This system has the potential for becoming a high throughput analyzer for approximately 100-150 hematology plus CD4 samples per day.

The PointCare lysing system (Erythrolyse/Stabilyse) has proven to be more effective in CD4 cluster presentation than the Drew lyse. The Drew lyse will remain onboard for the gold-free 5-part leukocyte differential. The Drew paddle mixers can be used to lyse samples for CD4 analysis with the Erythrolyse. Further optimization is to be done in the Excell 22 mixing chamber.

The Excell 22 optics has been modified to accommodate the CD4 immunogold assay. A new "Right-Angle Scatter" (RAS) detector has been added to the optical assembly for improved CD4 analysis over the Excell 22 "Super-Wide Angle" (SWA) Detector. A black matte finish has been applied to the interior of the optical assembly to reduce stray light. The Excell 22 does not currently have any integration on the detectors, but this may have to be implemented for enhanced CD4 cluster presentation.

Fluid delivery modules will have to be added to the Excell 22 to accommodate the addition reagents required for the CD4 immunogold assay. A gold reagent and accelerant delivery module as well as delivery for the Erythrolyse and Stabilyse will have to be implemented. There is an auto-sampler that PointCare would like to use for all systems being sold for CD4 analysis. This would allow the system to be operated for 30 samples without interruption.

Modifications to the Excell 22 analytical software will have to be made for CD4 cluster recognition as well as flagging criteria. The Excell 22 user interface will also have to be modified for CD4 analysis of patients and controls.

Some of the components of the Excell 22 are open and susceptible to dust and particulate collection. These components will have to be examined for the environment that PointCare plans to place these instruments. Internal control points for temperature, humidity, and door and cover sensors will also have to be addressed.

1. Purpose

   a. Drew Scientific currently sells an instrument by the name "Excell 22" that has the potential to utilize a CD4 gold assay. The purpose of this investigation is to examine the possibility of adapting the Excell 22 to analyze a CD4 gold assay and determine the necessary hardware modification to do so.

2. References and Attachments

   b. PointCare Lab Notebook PCT-1035, pages 1-2, 20-32

   c. PointCare Lab Notebook PCT-1040, pages 16-19

   d. Drew Scientific Visit Report 010506

   e. Drew Scientific Visit Report 021006

   f. Bikoue, A., et al. *Quantitative Analysis of Leukocyte Membrane Antigen Expression: Normal Adult Values.* Cytometry. Vol. 26: pages 137-147. 1996.

3. Test Results

   g. Description and Status of Testing:

Task #	Test Task	Critical Element	Schedule	Responsibility
1.	Decide between Drew RBC lysing reagent and PointCare RBC lysing reagent	Lysability and CD4 cluster separation	2/10/06	D. Barry
2.	Evaluate Excell 22 paddle mixers	Lysability and CD4 cluster separation	3/31/06	D. Barry
3.	Evaluate Excell 22 optics as platform for PointCare immunogold assay	CD4 cluster separation	3/31/06	D. Barry/ P. Hansen
4.	Evaluate Excell 22 data handling electronics and sample handling electronics	Flexibility necessary for CD4 assay	2/10/06	D. Barry
5.	Determine design options for immunogold dispensing	Small volume (~10 uL) fluid delivery	3/31/06	D. Barry
6.	Determine gates and regions for analytical software development	New gates for CD4 lymphocytes	3/31/06	D. Barry
7.	Evaluate Excell 22 user interface	CD4 analysis capability	3/31/06	D. Barry

8.	Determine dust-sensitive components of Excell 22	Particulate interference	2/10/06	D. Barry
9.	Determine compatibility of auto-sampler	Throughput expected, number of samples held, and sample volume delivered	2/10/06	D. Barry
10.	Evaluate internal control points in Excell 22	Complete hardware and assay control points	3/31/06	D. Barry

h. Significant Test Results

i. Both the Drew five-part differential lysing reagent and the PointCare lysing reagent (Erythrolyse II) are acceptable for red cell lysis. The PointCare lysing reagent did however produce greater CD4 cluster separation than the Drew lyse (figure 1). Please see below a legend for Excell 22 parameter numbers:

Parameter Number	Description	Angle
1	Low Angle Scatter (LAS)	~3°
2	Extinction (EXT)	0°
3	Wide Angle Scatter (WAS)	~8°
4	Super Wide Angle Scatter (SWA)/ Right Angle Scatter (RAS)	~30° - 45° for SWA, 65° – 115° for RAS

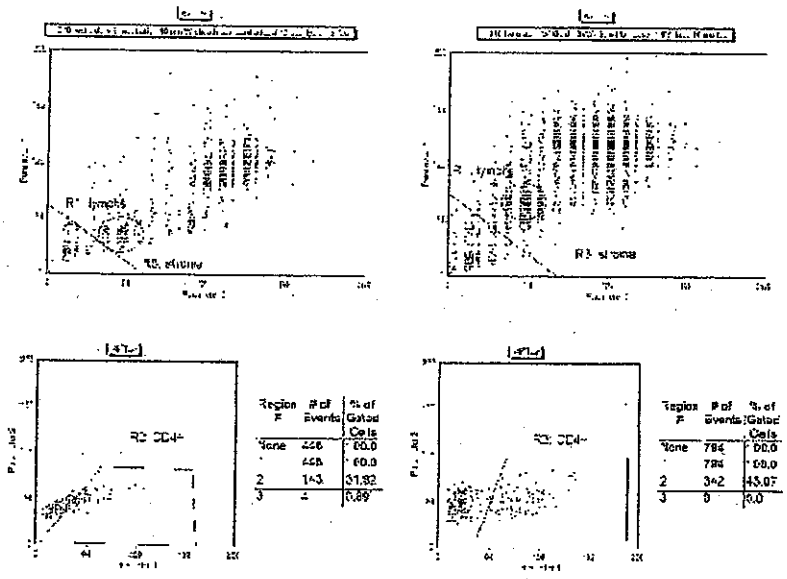


Figure 1: The plots above demonstrate that both the Drew lyse (left) and the PointCare lyse (right) can produce clean RBC lysis, but only the PointCare lyse presents a clear CD4 cluster.

ii. The paddle mixer and mixing sequence that exists in the Excell 22 did not provide sufficient mixing to completely lyse the red cells and present CD4 cluster separation similar to off line vortex mixing. A breadboard of the paddle mixer with a stepper motor to control mix speeds and times was developed to evaluate if the paddle mixer could be used with a different sequence.

The vortex sequence of 3 seconds mix with blood, gold, and diluent, then add lyse and vortex for 8 seconds, then add quench and vortex for 10 seconds is considered to be the standard to compare to [PCT-1035: 1-2]. All vortexing is done at 1700 rpm. The standard volumes are 50 µL whole blood, 50 µL diluent (PBS with 0.1% polybrene), 20 µL gold, 300 µL Erythrolyse II, and 133 µL Stabilyse [PCT-1035: 1-2]. An example of this sequence using an AuRICA for the analysis portion can be seen in figure 2.

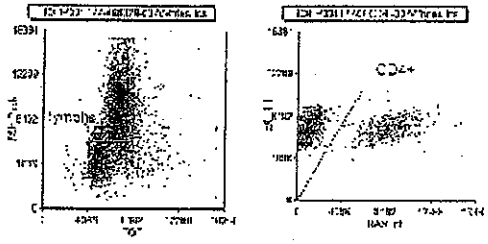
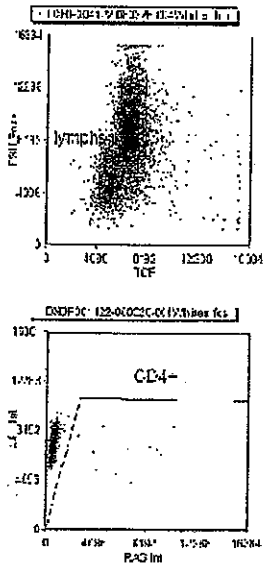


Figure 2: The plot above shows the Erythrolyse when vortexing is used to lyse the sample.

When the same sequence is used with the paddle mixer, a clean leukocyte differential can be seen when no gold or diluent are used (figure 3). When gold is added, the CD4 cluster is present, but there are some unlysed RBCs present (figure 3).


lymphes
CD4+

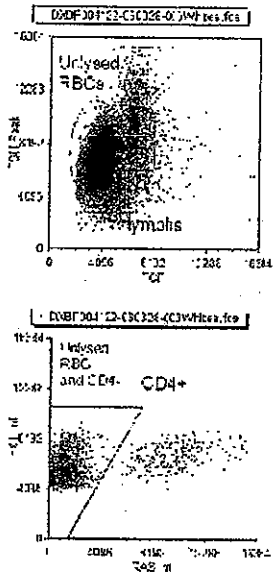
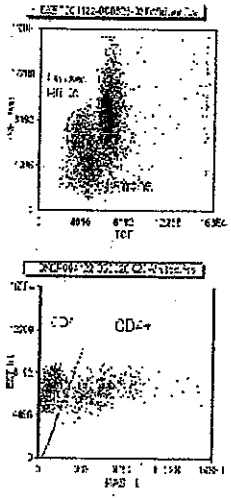
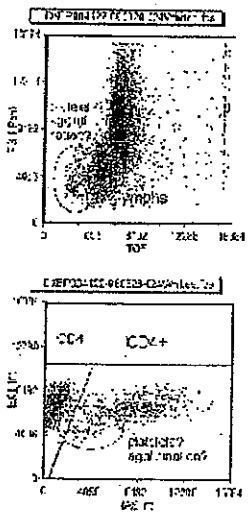


Figure 3: The left plot shows that when the paddle mixer is used with no gold or diluent, a clean WBC differential can be seen. The right plots shows that with the same sequence but with gold added, the CD4 cluster is present, but unlysed RBCs are present as well.

It is still possible to use the paddle mixer to obtain both an easily discernable CD4 cluster and a clean leukocyte differential. Some options for modification of the lyse sequence include lyse and quench volume adjustment, lysing time adjustment, and lyse mixing speed. Complete results from testing using these sequences can be found in notebook PCT1035: 20-32.




Lymphs
CD4
CD4+

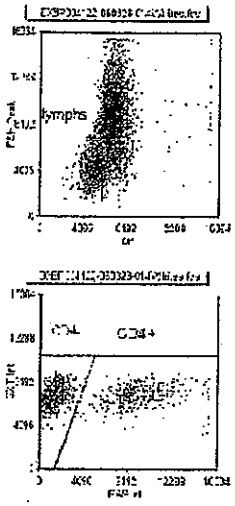


Figure 4: The left plot shows that when the lyse volume is increased from 300 to 400 µL, the RBCs are decreased. The center plot shows that when the mix speed is increased from 1700 to 3400 RPM, the RBCs disappear, but it looks like there may be some platelet aggregates or possibly agglutination of leukocyte fragments or protein. The right plot shows that when the lyse mix time is extended to 12 seconds, but the mix speed and volumes are the same, the RBCs tend to disappear.

Optimization of the paddle mixer should be done using the Drew Excell 22 mixing chamber. The geometry and material of the chamber is different than that of a 12mm polypropylene culture tube and the mixing may be slightly different. It may be necessary to modify the Excell 22 mixing chamber so that no reagent is lost through the bottom of the cuvette.

iii. The existing optics in the Excell 22 had to be modified to accommodate the CD4 assay. The Excell 22 optics currently has a " super-wide angle" detector that has a mask to detect eosinophils at 30° to 45°

(figure 5). To be able to see the CD4+ cells separate from the CD4-, the mask had to be removed to allow an angle of 30° to ~90°.

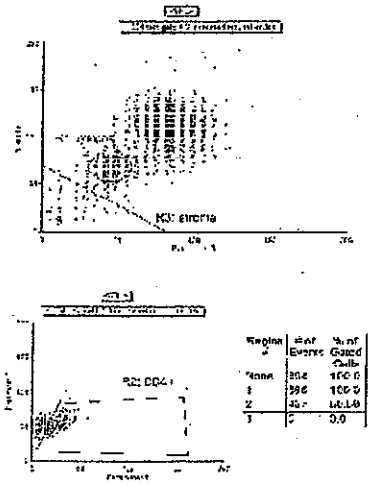


Figure 5: The plot above shows PointCare lyse with Excell 22 optics as manufactured today with a mask on the super-wide angle detector.

In order to see an improved CD4 cluster presentation, the gain for the super-wide scatter detector was nearly doubled. This did improve the visibility of the CD4 cluster, but also added noise. The scatter gain was then brought down to about 1.5 times the original gain and similar results were seen with slightly less signal (figure 6).

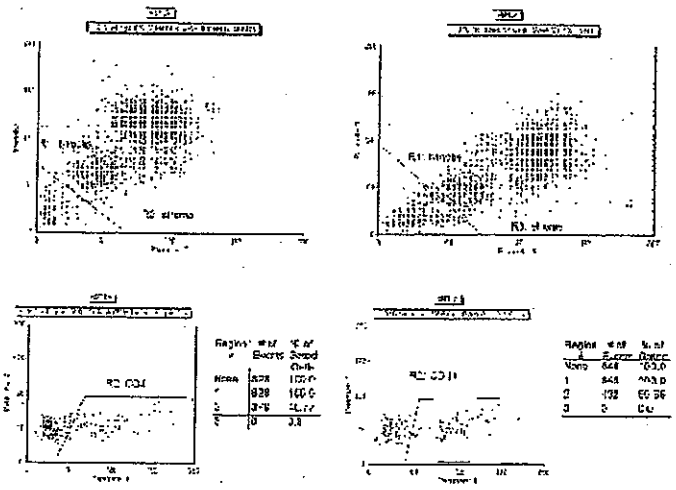


Figure 6: The left plot shows the mask removed and the gain doubled on the super-wide angle detector. The right plot shows a gain of 1.5 times the original. In both cases, an increased noise is seen.

The Excell 22 laser normally runs at about 2 mW. When the laser power was increased from approximately 3 mW to 4 mW (1.9V), cluster definition was improved without a significant increase in noise (figure 7). It may be necessary to use a higher powered laser to easily define a CD4 cluster. PointCare currently uses a laser running at 8 mW to visualize a CD4 cluster. The Drew system does have a PMT that may prevent the need for a higher powered laser. The beam profile in the Excell 22 optics is 200 μm wide by 20-25 μm tall. This appears to be acceptable for sizing the cells as well as producing enough signal for all detectors.

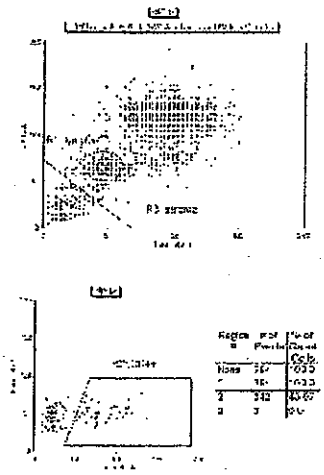


Figure 7: The above plot shows an increased CD4 separation by increasing the laser power without increasing the gains.

The PMT for the super-wide angle has a light collection lens. We removed this lens to see if we could eliminate an extra alignment step in manufacturing, as well as the need for an extra part (figure 8). It does appear that even with the lens removed, a CD4 cluster can be seen. Just to note, a different gold lot was used that may account for differences in CD4 separation from previous analysis.

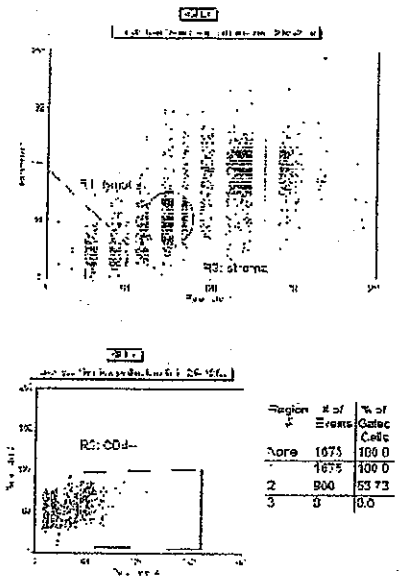


Figure 8: The above plot shows the CD4 cluster without a light collection lens.

There was a modified optical assembly at Drew with the internal walls of the optics covered with a matte black finish to reduce stray light. This increased the signal of the clusters and should help us in locating the CD4 clusters (figure 9).

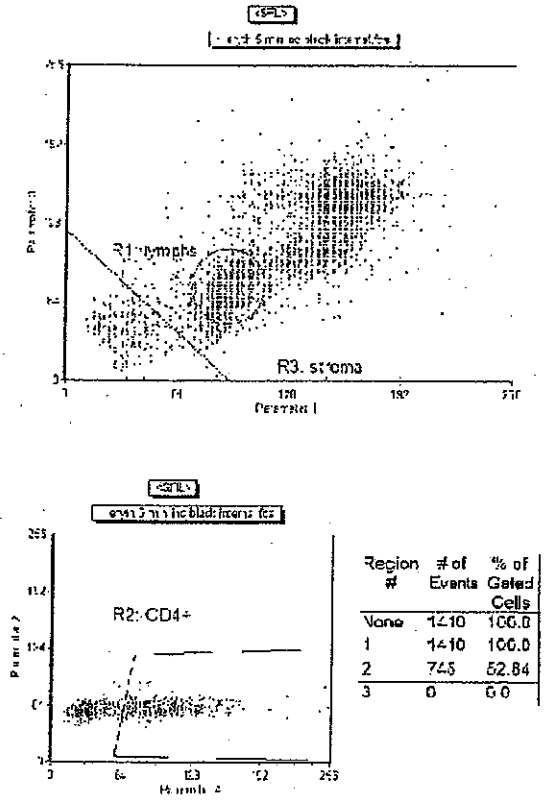


Figure 9: The above plot shows the CD4 cluster with a blackened interior and without a light collection lens.

In order to analyze both eosinophils (by use of the mask) and the CD4 cluster, an additional detector (PMT) was added to the other side of the Excell 22 optics. It is possible to identify eosinophils without the mask (figure 10), but the mask is an enhancement. The interior of the optical assembly does have a black finish to reduce stray light. The additional detector does have a light collection lens but there is no mask. The lens may not be necessary for the RAS detector, but more testing paying close attention to noise will have to be done. This detector is repositioned to be centered at 90° with a range at approximately 65° to 115°. A CD4 cluster could be easily seen using this optical assembly (figure 11) when the laser is

run at 1.5 mW. Although it is difficult to determine if increasing the laser power improved cluster definition in the case, previous testing has shown that this may be an improvement. It may be necessary to further increase the laser power for larger CD4 cluster separation.

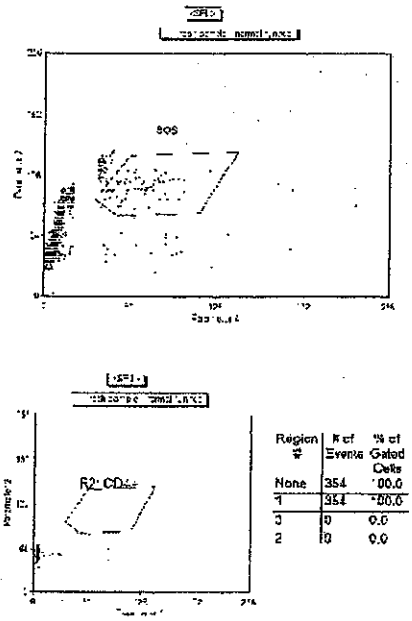


Figure 10: The plot above shows that when the Drew 5-part differential lyse is used with a sample without gold, the eosinophils are easily distinguished, even without the mask.

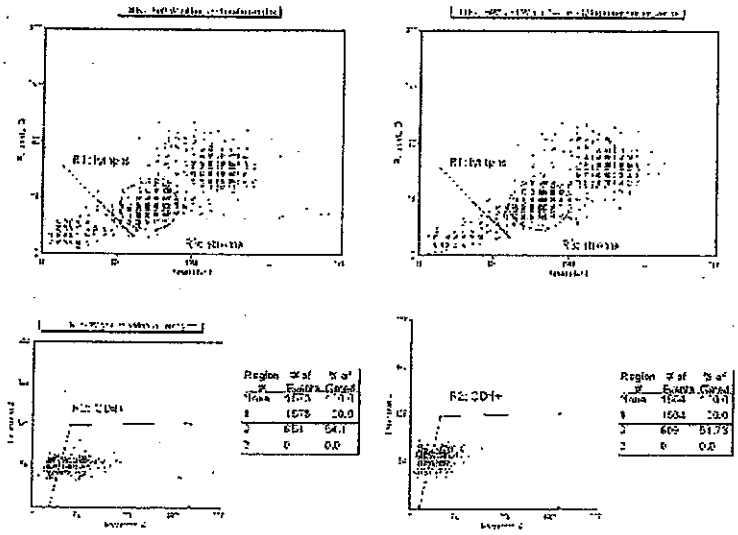
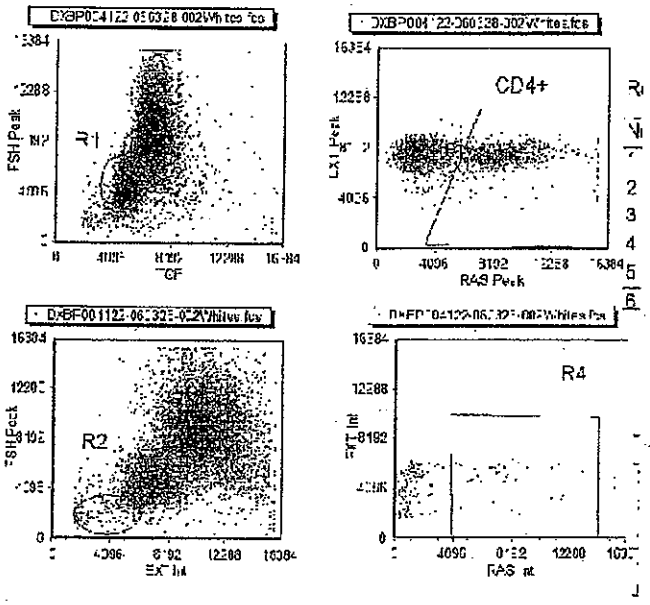
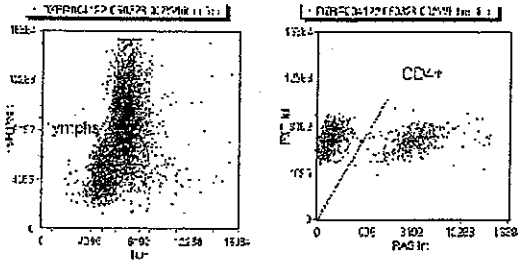


Figure 11: The left plot shows that when using the additional right-angle scatter (RAS) detector without a mask, a CD4 cluster can be seen. The right plot shows an increased laser power from 1.5 to 2 mW.

The current PointCare electro-optics design on the AutRICA System uses a higher power (8mW) laser and has analog integration on the RAS preamp. A slight improvement to the CD4 cluster presentation can be seen with higher laser power, but the majority of the enhancement is done by the integration (figure 12). For this reason, it may be necessary to add integration to the Drew optics for optimal cluster presentation.


R1
CD4+
R2
R4


CD4+

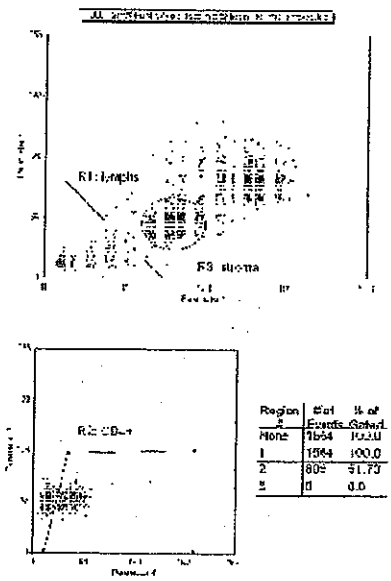


Figure 12: The three plots above are examples of a manual preparation of the Erythrolyse/Stabilyse system. The left and center plot is a sample analyzed with the PointCare optics and the right is using the Drew optics. The center plot demonstrates the increased cluster presentation when using integration. For this reason, it may be necessary to add integration or increase laser power on the Drew system for increased signal.

Additional information including testing procedures and results can be found in *Drew Scientific Visit Report 010506, Drew Scientific Visit Report 021006,* and *PCT 1040, pages 16-19.*

iv. The Excell 22 is currently going through a revision to replace obsolete electronics that may have been a concern to PointCare for future manufacturability.

The need to add the PointCare lyse reagents and gold delivery module present the need for I/O ports in the Excell 22. These ports are available for implementation of the CD4 assay fluid handling.

There is a new power supply design that will meet the PointCare business and marketing needs. A power budget of the Excell 22 is acceptable so that in case of a power failure, a sample may be completed and the system may

safely be shutdown with the presence of an Uninterruptible Power Supply (UPS). The possible use of an automobile battery pair for daily operation is still to be determined.

The data collection electronics only have peak detection (no integral channel). There is a benefit to adding integration due to increased CD4 cluster presentation. This will have to be explored further.

An onboard processor and touch screen monitor would be desirable for a future revision, but an external touch screen should be acceptable at this time.

v. The immunogold dispensing does not have to be done at a high precision (only ~10%). Syringes for immunogold and accelerant will have to be added to the Excell 22 for CD4 analysis. Because of the small volumes used, it may be necessary to add a pipetting system for the gold and accelerant reagents. The pipetting mechanism would also be necessary for the dried gold reconstitution. Attention to fluid line lengths and internal diameters are needed to ensure minimal loss of gold reagent to waste. In-line mixing may be needed for the blood, gold, and accelerant mixture.

A temperature control module for the bulk gold reagent will need to be added to the Excell 22. The bulk reagent temperature specifications have not yet been determined, but it is expected to be 2-25° C.

vi. The gates and regions for analytical software have been established for CD4 analysis. The lymphocyte gate can be placed in the low angle vs. wide angle scatter parameters. After gating on lymphocytes, the CD4 cluster can be seen using extinction vs. a modified super-wide angle (right-angle scatter). Because analysis will be dual platform, a conservative (small CV) gate can be chosen for purity of lymphocytes to obtain a CD4%. This can then be applied to the lymph count obtained by either the impedance channel or the gold-free lymph count from the cytometer.

vii. The Excell 22 user interface (UI) will have to be modified to accommodate a CD4 testing option, as well as a hematology only test. The UI will also need to be modified for CD4 and external controls.

viii. Currently, the Excell 22 has open cuvettes that may allow dust to enter the mixing chamber. A cover will have to be developed to prevent contamination to mixing chambers.

ix. The auto-sampler in existence for the Excell 22 can operate uninterruptible for 30 samples at a time. This is an expected time of 90 minutes of automated operation for a CD4 test. There is a barcode reader for positive sample identification. No testing has been done, but modification for a CD4 assay appears favorable.

x. Internal control points may have to be implemented. Currently, door

and cover sensors, reagent level sensing, database verification, and volume check (auto-sampler only) exist, but some anticipated hardware controls for temperature and humidity are to be introduced later. There are existing flags for hematology parameters but new flagging criteria and control points for CD4 analysis will have to be included as well.

i. Other Test Results

n/a

4. Discussion

j. The integration may be necessary to overcome differences in CD4 cluster presentation. Patient to patient variability can be as much as 30% due to number of CD4 antigen sites. A study done on normal patients by Bikoue et al. found that the average number of CD4 antigen sites on a T-Lymphocyte is 47,000 ± 14,000 (±30%). The difference in number of CD4 antigen sites could present differences in CD4 cluster presentation. A patient with a low number of antigen sites could have large overlap between CD4- and CD4+ which would be difficult to resolve.

The integration also would decrease noise on the RAS channel. The CD4 absolute count is less than 50 counts/μL in many patients who are in late stage AIDS. This is in the range of noise on the RAS detector when using peak detection only. By adding integration, the low CD4 counts should be easier to detect.

5. Conclusions

k. The Excell 22 system can be modified to accommodate a CD4 immunogold assay. The Excell 22 can be adapted to meet the needs of a developing world market for high volume CD4 analysis.

6. Recommendations

l. The Erythrolyse II/Stabilyse lysing system should be used to obtain a CD4 cluster on the Excell 22. The Erythrolyse II produced a larger separation between the CD4- and CD4+ clusters than the Drew lyse.

m. The mixing sequence with the Drew Excell 22 paddle mixer needs to be optimized for the mixing chamber to be used. This can be developed using the mixer breadboard and an AuRICA instrument and compared to vortexing as a standard.

n. The Excell 22 optics can be used for the CD4 immunogold assay with the following modifications:

i. An additional PMT now should be placed on the opposite side of the " super-wide angle" detector to act as a "right-angle scatter" detector. There should be no mask on this side and testing will need to be done to determine the need for a light collection lens.

ii. The interior of the optical assembly should have a black finish.

iii. A power increase or change to the current Excell 22 laser may be necessary. This should be pursued as part of assay and system optimization when rapid sample delivery is available. Options for integration on the RAS detector will also have to be examined. The beam size appears to be appropriate for CD4 analysis.

o. Create new module for handling PointCare lyse reagents and gold delivery module. Data handling for the additional detector must be addressed as well.

p. A bulk gold reagent must be developed for this system. Number of uses, reagent drying method, reconstitution method, and temperature control must be developed at PointCare.

q. Gating strategies for the CD4 cluster need to be developed for the Excell 22. Only a CD4% will be necessary for this part of the analysis. There currently is no integration for scatter parameters in the Excell 22. This will create more globular cell clusters (CD4- and CD4+) and may be more easily analyzable by histogram analysis methods.

r. Modifications to the Drew UI must be done to accommodate CD4 whole bloods and controls.

s. Dust covers for open cuvettes should be designed to prevent particulate interference.

t. The auto-sampler sequence will have to be modified to allow sampling for CD4 analysis.

u. Internal control points for hardware and flagging criteria for CD4 analysis must be

implemented.

Dear Roger,

Our meetings here with Rich, Harry, and Frank really moved right along, and I think everyone is on the same page.

I have attached Don Barry's report regarding the system work that you, Romiya, and he did in Dallas. I think that there is one very important new conclusion which you can read on Page 14 and 16. I can summarize it here:

Make no change in laser power from the current Excell 22 configuration. The advantage is of course that no current hematology analysis will need to be changed in the new system. However, even though with the current laser power there are two clusters, there really is insufficient CD4 cluster separation. If, however one was to add an integrator to the new PMT electronics, the cluster separation should be fine.

Here is why we say the cluster separation is "insufficient". The problem with CD4 analysis is that there is a 30% CV in the mean number of CD4 receptors on lymphocytes from patient to patient. It has nothing to do with HIV or the stage of the diasease. This means that the CD4 positive cluster position on the right angle scatter axis moves plus and minus about 50% if you take into account extreme cases. For this reason, you need a pretty big valley between populations when you are looking at the "average" patient in order to deal with the extreme low antigen density patients.

If you look at Don's dot plots on page 14, you will see the following illustration: The left-hand plot is the PointCare optics and peak detection for the signals. The right-hand plot is the Drew (new) optics and also peak detection for the signals. The plots are similar inasmuch as there is not a wide valley between the two clusters. The middle plot is the same sample and same run as the left-hand plot with PointCare optics, but analyzed through an integrator (we get both peak and integral outputs on PointCare). You can see the dramatic improvement in the size of the valley with the integrator.

Don and I propose that we include an integrator on the new PMT output. We have had a lot of experience with flow cytometry integrators, and in fact we have an excellent contractor near here that builds them for us. I am sure that he could design and build the appropriate board for you very quickly.

Let either Don or me know if there are any changes or additions that you would like to make to the report.

Thanks, and we are looking forward to seeing you in Boston.

Peter

EXHIBIT 4

From: Petra Krauledat
Sent: 5/9/2006 10:22:14 PM
To: Harry Rimmer
CC: Richard J. DePiano; Ken Pina; Roger Bourree; Frank Matuszak; Peter Hansen; Dan Oconnor Road Runner Account
Subject: RE: The Agreement

Harry,
I am attaching the agreed upon product specifications which will be Annex 1 (this document was generated in cooperation between Peter, Roger and Don Barry and it was reviewed by Andrew Kenny and Dan O'Connor). The document answers your question regarding the PointCare labeled instrument to be limited to white cells, hemoglobin and CD4. This is exactly how I propose to distinguish between our two companies products.

Earlier today Don Barry sent the timeline to go along with the product specifications. In the current Agreement draft this timeline is to be part of Annex 1. This timeline was also reviewed by everybody mentioned above and agreed upon.

Regarding the change of control and a right for Drew to manufacture the reagents, I suggest to use a "reasonable and customary" royalty rate rather than a fixed number. I believe that the market is too hard to predict today to fix a royalty rate. It could be to Drew's disadvantage in certain markets if prices get pushed low.

Call me if there are any questions.
Petra

Petra B. Krauledat Ph.D.
President and CEO
phone 518-256-8642
fax 508-281-6930

From: Harry Rimmer [mailto:hrimmer@escalonmed.com]
Sent: Tuesday, May 09, 2006 5:16 PM
To: Petra Krauledat
Cc: Richard J. DePiano; Ken Pina; Roger Bourree; Frank Matuszak
Subject: The Agreement

Petra, I'm talking to the attorney in the morning to brief him on the agreement. I expect to get an internal draft within 24 hours. Rich needs to see a complete document before he can sign off on it. We hope to speak to C2 tomorrow, but haven't been able to contact Henri yet.

I'll include some wording in the agreement about our option to manufacture the assay if PoinCare is bought out. For this to be meaningful we need to agree a royalty payment - I would suggest 5%.
You explained in our recent phone conversations that you would disable the "reds" in the HT instrument. Would you agree to only selling instruments that are limited to analyzing the whites, CD4 and CD4% ?
Rich and I will be talking to you later this week about the investment opportunity.
I'll be in touch
Harry

Attachment: petra.JPG
Attachment: CBPR-008 Rev 2.doc

EXHIBIT 5

From: Harry Rimmer
Sent: 5/15/2006 8:47:43 PM
To: Roger Bourre (remote)
CC:
Subject: PointCare Annex

Roger, Please confirm that this product spec is correct. Is this just for the PontCare version, which has no red channel?
Also confirm the timeline is OK from Don - I looked at it in Twiddlebit.
See you tomorrow
Harry

Attachment: PointCare03 A01 Annex 1 Attach A Dev mkt.doc

EXHIBIT 6

From: George Chappell
Sent: 11/22/2007 1:26:11 AM
To: Don Barry (debarry@pointcare.net); Peter Hansen (phansen@pointcare.net)
CC: Doug Nickols; Gary Young; Jerry West (remote); Roger Bourree
Subject: CD4 PMT position study

These samples were run with the new gold reagent that you just sent us. I screwed a piece of aluminum to the top of the flow cell as a position reference to make measurement with my calipers easier. A location of 0.165 inches is the optimum point that we found a couple of months ago operating at 40 degrees C.. Measurements greater than 0.165 indicate movement away from the LASER and less than 0.165 is toward the LASER. Please review and let me know which one wins the beauty contest. I have included the fcs files if you want to take a closer look.

GDC

Attachment: Position_Study_FCS.ZIP
Attachment: CD4_PMT_Position_Study.pdf

EXHIBIT 7

6-13-06

(2)

SAMPLE PREP.

45 WHOLE BLOOD ±10%

45 PCC ±30%.

20 GOLD REAGENT +0 -30%

SEQ. IS NOT CRITICAL.

THIS MIX STEP IS NOT CRITICAL 3-5 SEC. VORTEX MIXING.

PADDLE MIXING.

37°C REACTION CHAMBER TEMP. CUVETTE

3 min. MAX INCUBATION BEFORE LYSING.
(PREFERABLE TIME 45 SEC - 60 SEC)

2 PASS TEST (1ST NORM. TEST 2ND CD4- TEST)
RUN NORM. TEST DURING INCUBATION

300µL
ACIDIC CD-4 LYSE ±10%.

MIXING & TIMING CRITICAL. 10 SEC MIX

STEPPER MOT. SPEED OF MIX CRITICAL. MAY REQ. RAMPING.

135
ADD QUINCH µl ±10% 10 SEC.

NEUTRAL PH & OSMOLALITY.

GOLD REAGENT

GOLD REAGENT TURNS ACRYLIC BROWN AFTER ONE MONTH.
NO AFFECT ON TYGON OR DELRIN.

REAGENT CONTACT TIMES (SHORT) MAKE REACTION MINIMAL.

EXHIBIT 8

Drew Scientific Inc.

Memo

To: Andrew Kenny

From: Karl Gu

CC: Gary Young, George Chappell, Jerry West

Date: August 29, 2006

Re: EXCELL 22/CD4 Software Time Estimate

Following tables list available resources and estimated time for the EXCELL 22/CD4 software project.

Resources

Name	Company
Karl Gu	Drew Scientific
Jen Waite	PointCare Technology
Jason Werner	Capshire Technology

Current task list and time estimate for EXCELL 22/CD4

Task	Estimated Time in Weeks	Time Spent So Far in Weeks
User Interface	4-6 (Karl), 12-16 (Jen)	1 (Karl), 2 (Jen)
Hematology.dll	1 (Karl)	0
CD4.dll	4-6 (Karl)	0
Service Software	4 (Karl), 12 (Jason)	0.5(Karl), 1(Jason)
Optics & Sequencer	2 (Karl)	0
Misc UI Util	1 (Karl), 1 (?)	0
Integration, debug	1-2 (Karl)	0

Summary:

So far, I have only been able to spend about one and half week to work on the project.

EXHIBIT 9

PointCare Technologies Inc.	TECHNICAL REVIEW MEETING	Document No.: HT-00XX	Rev. A
Effective Date:	TITLE: AURICA HT USER INTERFACE TASKS	Page: 1 of 119	

Review Meeting Minutes

Title of Project	High Throughput System User Interface
Design Phase	Phase 1
Date	July 13, 2006
Project/Review Leader	Andrea Desrosiers

This review is a (check one):

☑ Technical Review ☐ Design Review ☐ Verification Review

☐ Validation Review ☐ Final Design Review /Market Release Design Review

Attendees/Approvals:

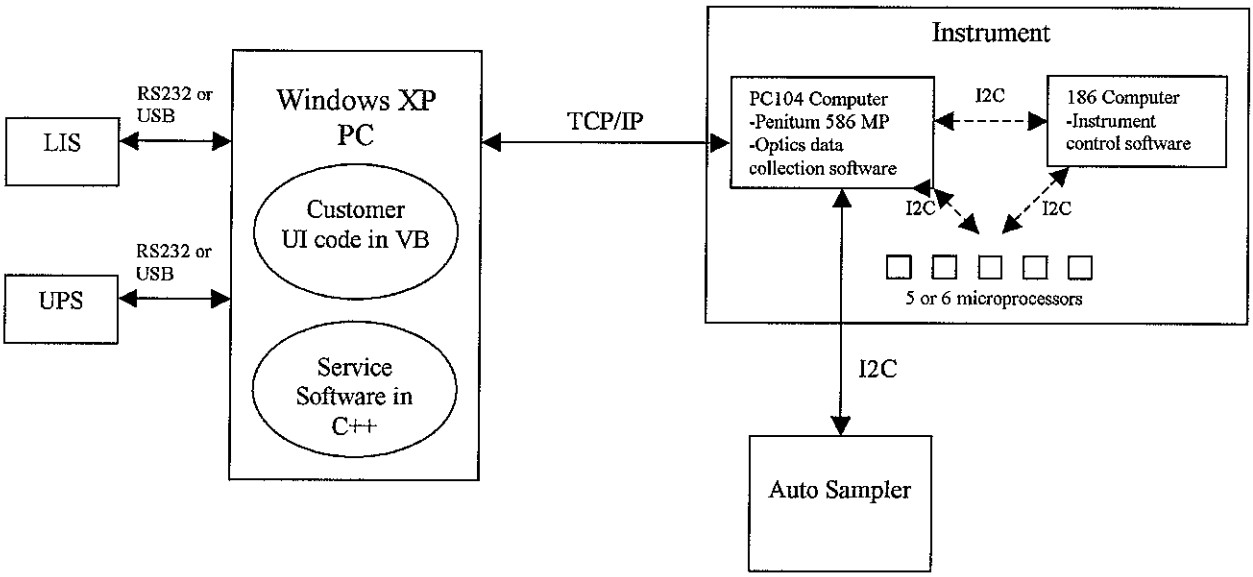
Name	Signature/Approval	Title	Review Function
Karl Gu		Sr. Software Engineer, Drew Scientific	Project Leader
Jennifer Waite		Software Engineer	Developer/Originator
Andrea Desrosiers		Software Manager	Technical Review
Don Barry		Scientist/Engineer	Project Manager
Maurice Doire		Director of Quality Systems	QA/QC

Summary:

Karl Gu, Sr. Software Engineer at Drew Scientific, visited PointCare to discuss the architecture of the Drew Excell 2280 customer software as well as the development work needed to adapt the Excell 2280 User Interface to the needs of PointCare's high-throughput instrument with CD4 reporting.

Items discussed

1. Pictorial overview of the Drew Excell 2280 hardware & software architecture.



2. Responsibilities

   a. PointCare will be responsible for modifying Drew's customer user interface software to meet the requirements of the high-throughput instrument with CD4 reporting.

   b. Karl Gu and his team at Drew will be responsible for sequence and service software changes.

3. User Interface Development Tools:

   a. User Interface development: Visual Basic 6.0

   b. Language integration: Multilizer Language Manager Software

   c. Database: MS Access 2000 (converted from Access 97)

4. Other Requirements
    a. The screen resolution for the user interface will be kept at 800 x 600 for the initial release.
    b. There will be a single executable for the PointCare and Drew user interface for the initial release.
    c. For patient sample runs with CD4 reporting, there will be 2 FCS files created: one for the 1st pass with no gold, one for the 2nd pass with gold (i.e. 186.fcs & 186_CD4.fcs).
    d. Option for user to run sample in "Direct Mode" (open tube) will be removed.
5. User Interface Change Detail
    a. General Screen Requirements
        i. Remove function key specifiers from above all buttons. Possibly add them to background bitmap of each button or just define function keys in user manual.
        ii. Make buttons bigger for touch screen use
        iii. Use "Back" or up arrow icon instead of "Exit" on all F9 buttons except on Main Menu.
        iv. If there is time, change all date entry text boxes to drop down menus for localization issues.
        v. ***Question: Should we remove the Worklist and Mode status fields from all screens since these will not change?***
    b. Create initial Login Screen
        i. 2 users levels: Administrator, Technician
        ii. Login Screen will have a drop down menu for choosing a user name
        iii. Initial login after install will contain only one user: "Admin"
        iv. "Admin" user will have an unchangeable password
        v. "Admin" user can create multiple Technician users and change their passwords.
        vi. All prompts for operator initials need to be removed because operator username will be used.

c. Main Menu

i. Add 2 more progress bars for monitoring Gold and CD4 Reagents Fluid Levels.

ii. Run button will bring up Auto Sampler Screen instead of Run Menu Screen

iii. Calibration button grayed if user is a Technician

d. Startup And Shutdown Menu

i. Add 2 more progress bars for monitoring Gold Reagent and CD4 Reagent Pack Fluid Levels.

ii. Add "Logout" button which will bring up the login screen

iii. After shutdown sequence is completed, bring up the login screen

iv. ***Question: What happens to "Wake Up" function if user is logged out automatically after shutdown is completed?***

e. Worklist Menu

i. Edit Worklist Menu

1. Remove "Add Sample" button

2. Reorder remaining buttons: Add Sample Carousel 1, Add Sample Carousel 2, Add Sample Carousel 3, Revise Selection, Delete Selection

ii. Add Carousel 1/2/3 Menu

1. Add "Sample Collection Time" field

2. Add radio buttons for "CBC only" and "CBC with CD4", default = "CBC with CD4."

3. Remove Male/Female buttons and add Gender drop down list with values: Male, Female, Unspecified

4. Add buttons for CD4 Low Control and CD4 Normal Control

5. Reorder Buttons: Find Match by Patient ID, Find Match by Name, Low Control, Normal Control, High Control, CD4 Low Control, CD4 Normal Control, Save, Exit

f. Auto Sampler Screen

i. Add progress bars for monitoring all reagent fluid levels

ii. Add "Run Background" button

iii. Need to define and support barcode format of CD4 Controls (and CBC-Only vs. CD4 runs?).

iv. ***Question: Should we remove "Stat Direct" and "Stat Saver" buttons since they will not be used?***

v. ***Question: If barcode reading is turned on how is run type specified? (CBC only or CBC with CD4)***

g. Datalog Menu

i. Add 2 new parameters to Datalog table (and db): CD4, CD4%

1. Insert CD4 after EOS and CD4% after EOS%

ii. Unsupported params will show up as blank in Datalog table and will be NULL in database.

iii. Add "Type" column to Datalog table (and db) for CBC only or CBC with CD4

iv. Transfer Function

1. add CD4 and CD4% to data stream

v. Print Functions

1. Add CD4 and CD4% to all printouts

2. Add CD4 and CD4% to all statistic calculations

vi. Find Menu

1. Add "Find Date" button to allow user to search by a date

vii. Change Function

1. do not change Datalog table cell heights if user clicks this button

h. Results Display

i. Add CD4 and CD4% result fields – keep blank for CBC only

ii. Change "Previous" and "Next" buttons to icons to make room

iii. Move Flags and Alert boxes to the right, under plots

iv. Add button that toggles between "Show CBC" and "Show CD4"

1. When "Show CBC" clicked, 3-D plot shows EOS
2. When "Show CD4" is clicked, 3-D plot shows CD4
3. If run is CBC only, 3-D EOS plot should be shown with "Show CD4" button invisible.

i. Results Printout

i. If run is CBC only, keep current printout

ii. If CD4 run, show 2-D CD4 plot instead of 2-D EOS plot

j. Calibration Menu

i. Add "Calibration History" button which will show a Calibration Log like Maintenance Log

ii. Calibration Run Menu

1. Run button brings up Auto Sampler Screen
2. Change "Load Diskette" button to "Browse" so user can browse for calibration file.
3. Remove "Load Remote" button
4. Add drop down with values 1-8 to specify the number of calibration runs to complete.

iii. Calibration Summary

1. add Accept/Reject button which will add/remove sample from calculation and automatically recalculate mean and factor values
2. A minimum of 3 samples must be accepted for calculation

k. Quality Control Menu

i. Add 3 new buttons: CD4 Control Menu, CD4 Levy Jennings Chart, CD4 Control Data File

ii. Reorder parameter columns in Control Data Table to match Datalog Table

iii. CD4 Control Menu

1. A maximum of 24 lot #'s can be saved in the table
2. Add Control Screen
    a. Change "Diskette" to "Browse"
    b. Need to find out format of diskette to be able to create QC range files at PointCare.
    c. Remove "Remote" button
3. Add Control – Manual Screen
    a. Add "Level" field for user to specify Low or Normal CD4 Control
    b. Add fields for user to enter ranges on this screen rather than having separate buttons to enter ranges for each level

iv. CD4 Levy-Jennings Chart

1. remove level buttons and replace with "Select" button.
2. adjust LJ lot# and months tables
    a. make sure all column headings are left aligned
    b. increase table width so that no fields get cut off

v. CD4 Control Data File

1. remove level buttons and replace with "Select" button.
2. adjust lot# and months tables
    a. make sure all column headings are left aligned
    b. increase table width so that no fields get cut off

3. Under "Review Data", change "Write to Diskette" to "Write to File".
    a. Allow user to browse to location to save file

l. Maintenance Menu

i. Move "Sample Status" button to F4 position

ii. Add CD4 Related Events (Reagents, Controls) to Maintenance Log

iii. Reagent Functions

1. F2 should be "Prime Diluent" button
2. F3 should be "Prime Sheath" button
3. F4 should be "Prime Cleaner" button
4. F5 should be "Prime Lyse" button
5. F6 should be "Prime Gold" button
6. F7 should be "Prime CD4 Reagents" button
7. F8 should be "Replace Reagents" button
    a. Add 2 buttons to replace Gold and CD4 Reagents
    b. Remove text box for operator initials
    c. ***Question: Will our reagents have a code?***

iv. Preventative Maintance Functions

1. *Question: What preventative maintenance functions will exist for CD4?*

v. Sample Status

1. Add field for "CD4 OC Count" for 2nd pass total count
2. Add fields for "CD4 Start Rate" and "CD4 End Rate"

m. Auxiliary Menu

i. Add fields for CD4 and CD4% in Patient/Action Range Screens

ii. Fix window pop up when "Printer" button is pressed

iii. Advanced Setup

1. button hidden on Auxiliary Menu screen if user is Technician
2. Change Lang button to "Choose Language"
    a. Choose language from a drop down menu
3. Remove "Error Code" column from System Log Table (and db)
4. Add "User Management" button

iv. Service Menu

1. Service button hidden on Auxiliary Menu screen if user is Technician
2. Operation Setup Screen
    a. Remove "Operating Mode" frame
    b. Remove "SSD Sampler" option from "Miscellaneous" frame
    c. "CN Free Lyse" option should be true by default
    d. Change "Control Mode" frame to "CBC Control Mode"
    e. Add "CD4 Control Mode" frame with same 2 fields
3. Shipping
    a. Remove prompt for initials
4. Constants Setup
    a. Impedance Contants
        i. Remove Auto Sampler Constants
        ii. Move Serial Number to top of screen
        iii. Have "Create Database" button allow user browse to location to save file.
    b. Special Constants

i. Add new frame called "CD4 Reagent Stability"

1. add fields for Gold and CD4 Reagents

6. Database Fixes

a. Resolve ambiguity internally for patientID vs. sampleID in barcode mode

b. Move EOS column to be before BAS column in master DB to match Datalog table.

c. Temp Control Table design should match Control Table design in master DB.

Action items:

Task	Person Responsible	Status	Date due
Determine how to differentiate between CBC and CD4 runs with barcodes turned on (include in barcode?).	PointCare/K. Gu		TBD
Determine effect login has on "Wake up" function.	J. Waite/K. Gu		TBD
Answer remaining questions in this document.	K. Gu		TBD
Modify Drew's DB document with new changes.	J. Waite		TBD
Populate DB with CD4 data.	J. Waite		TBD
Change Screen Menus w/o functionality.	J. Waite		TBD
Generate Screen/Menu change document.	J. Waite		TBD

Implement print functions.	J. Waite		TBD
Build remaining functionality.	J. Waite/K. Gu		Late August, 2006
Detection of power outage from within UI	J. Waite/K. Gu		TBD
Provide additional data for monitoring Mono center shift	A. Desrosiers/D. Barry		TBD
Get clarification about existence of TOF signal	K. Gu		TBD

☐

EXHIBIT 10

From: Karl Gu [kgu@mwi-danam.com]
Sent: Wednesday, August 02, 2006 1:20 PM
To: Jennifer Waite
Subject: RE: Finished Meeting Minutes Doc

Jen,

Thanks.

Karl

From: Jennifer Waite [mailto:jwaite@pointcaretechnologies.com]
Sent: Wednesday, August 02, 2006 1:12 PM
To: Karl Gu
Subject: Finished Meeting Minutes Doc

Hi Karl,

Here is the copy of the finished meeting minutes. This version is going to be released through our QA system.

-Jen

Jennifer Waite

Software Engineer

PointCare Technologies, Inc.

tel: (508) 281-6926 x15

fax: (508) 281-6930

work: jwaite@pointcare.net

personal: jwaite@alum.wpi.edu

EXHIBIT 11

Document Title: CD4 Customer Software Project Status Meeting

Author: Jason Werner

Date: December 11, 2006

Summary:

This document describes the points discussed during the meeting between Drew Scientific and PointCare, along with the action points for each person attending.

Attendees:

Name	Inital	Title	Company
Karl Gu	KG	Software Engineer	Drew Scientific
Andrea Desrosiers	AD	Software Manager	PointCare
Jennifer Waite	JW	Software Engineer	PointCare
William Ross	WR	Validation Manager	Drew Scientific
Jason R Werner	JRW	Software Developer	Capsher Technology

Meeting Topics:

1. **Validation**

Points Discussed:

- It was decided that both PointCare and Drew Scientific would be responsible for writing their own validation procedures.

Action Items:

- WR is responsible for the validation document for Drew Scientific.
- AD is responsible for ensuring that the validation document is written for PointCare.
- Drew Scientific will provide PointCare with the current validation document for the analyzer.

2. **Integration**

Points Discussed:

- JRW is responsible for the integration portions of the software project. This currently consists of helping with any integration issues related to the User Interface, CD4 dll, ActiveX controls, calculation utilities, autosampler logic, etc.

Action Items:

- JRW will keep in contact with PointCare to ensure that there are now integration problems.
- JRW will assist Jennifer Waite with any Autosampler logic questions and ensure that the code logic is correct.
- JRW will complete and send ActiveX controls to PointCare and assist with integration of each control.

3. PointCare Issues

Points Discussed:

- Screen resolution of 800X600 looks bad on current touch screens.
- PointCare needs to determine barcode format for CBC/CD4 controls and samples.
- Need to determine when the computer is operating off of UPS.

4. UI Tasks Remaining

Points Discussed:

- Each task written in the Aurica HT User Interface Tasks document was reviewed by JRW and Jennifer Waite.
- Graphics will be changed on all screens.
- Unused control buttons will be hidden on menu.

Action Items:

- JW will make a check list for each item remaining so that it can be checked off as it is completed.
- JW is working on having the UI tasks completed by the end of January.
- JW is responsible for modifying all screens to use the new graphics.
- JW will implement hiding of unused buttons.

5. Image Buttons

Points Discussed:

- Image buttons will contain both an image and text. The text will be on the lower portion of the button.
- Image display will be configurable so that it can be enabled and disabled to meet both PointCare and Drew Scientifics needs.
- All buttons on main screen will contain images.

Action Items:

- Dennis Chappell will design new image buttons that are square instead of round. Along with changing the shape of the button he will add a text area to the lower portion of the button.
- JW will integrate the new buttons into the software and make the image display configurable.
- JRW and JW will look through the buttons on the other screens to determine which ones will have images along with text.

6. Results screens

Points discussed:

- The software was modified to use only *one* results screen, but it was decided to use *two* results screens to remove any confusion in the logic behind the scenes.

Action Items:

- JW will modify the software to use two results screens instead of one to remove any confusion.

7. Calibration Samples

Points discussed:

- Calibration samples will be run separate from other samples.
- Calibration samples will be placed in the one position of the carousel.
- The logic for running the calibration samples will be similar to the batch processing.

Action Items:

- JW will modify the software handle configuration a calibration sample. The user will be able to define the number of times a calibration sample is processed.

8. Autosampler Logic

Points discussed:

- The autosampler logic was discussed and detailed by KG, JW, and JRW.
- Three different logical procedures were discussed: Preparing Work Queue, Running a Batch, and Running a Stat.

Action Items:

- JRW will create flow charts detailing the basic logical procedures followed for each scenario.
- KG will verify flow charts.
- JW will implement logic in software.

9. Installation

Points discussed:

- The installation procedure will need to be modified for the Aurica software. There were questions related to how this can be modified.
- The software will need to be installed from a USB removable drive.

Action Items:

- JRW and AD? will be looking into how this is currently being done and figure out how this should be modified.

10. CD4 Algorithm

Points discussed:

- The API for the CD4 dll was discussed, which consisted of three basic functions: *LoadCD4Param, CalculateCD4,* and *ReadCD4.*
- Also discussed was the integration of the dll into the existing architecture. The CD4 dll will be available to both the CBC dll and the VB app.

Action Items:

- AD will be working with another person from PointCare on implementing the discussed interface for the CD4 algorithm dll.
- JRW will be assist with any problems or questions related to integration of the dll into the software.

EXHIBIT 12

From: Andrew Kenney
Sent: 7/21/2006 8:55:42 AM
To: Karl Gu
CC:
Subject: Re: CD4 project resource

Karl

Now you know what you need, can you give me an approximate cost? We need to move quickly and Harry will approve the expenditure but only with an estimate for the budget.

Andrew

PS I would like to talk to you later - I have a call with Jerry and George at 9.30.

Karl Gu wrote:
> Hi Andrew,
>
> Now I have a better view of how much software work that we need to do and
> feel strongly that we need additional resources.
>
> PointCare team will do most of the User Interface with lots of help from my
> side even they are good team as this is something new for them. They have a
> team of three people, one of them is senior software engineer. From time to
> time, they hire another part-time graphics designer to do the screen
> designs. Other than help the UI, for my part, I need to do the service
> software which has the new algorithms, some additional flags, support new
> fcs file, new communication sequence with PC104. Second major piece is PC104
> optics software that collects the additional data with modified collection
> method (fixed time collection and real count collection, etc.) and support
> the new communication. The third big piece is the sequencer software, there
> are changes to run the new sequences, etc.
>
> In short, there are more than I can handle in the planned time frame. Thus,
> I request to get some help from contractors to work with me in the service
> software part. We may need to consider to get one contractor for 10 to 12
> weeks.
>
> Regards,
> Karl
>

EXHIBIT 13

From: Karl Gu
Sent: 10/18/2006 7:13:41 PM
To: Andrea Desrosiers
CC: debarry@pointcare.net
Subject: RE: PCT Internal Data

Hi Andrea,

I will supply you a CD4 dll plus utility that display the separation of CD4+ and CD- some time next week. You can replace the calculation part in the dll to start the algorithm work. There are only fixed cut in the dll right now.

I did spend sometime to look the test results in FCS Express V3 and have a few observation:

The CD4+ and CD4- population are not evenly distributed

There are some cells in the lower left corner and my guess is that they are Lym instead of Plt if we believe the reference counts are good

The CD4+ and CD4- separation line does not pass the origin

We could use two primary gate for the first step and compare each other.

We need to ignore the regions that not our interest to speed calculation

Regards,
Karl

From: Andrea Desrosiers [mailto:adesrosiers@pointcare.net]
Sent: Wednesday, October 18, 2006 1:28 PM
To: Karl Gu
Subject: RE: PCT Internal Data

Hello Karl,

I'm sorry for the delay. I wanted to get the released version of a report finished before I sent it to you. The report on the preliminary analysis of the in-house testing is attached. Hopefully, this will help you to understand what we've been seeing. The reference value on the spreadsheet you have are from an external testing lab called Quest Diagnostics. I think that they use a Coulter XL and a Coulter Gen-S to get the CBC+ CD4 counts.

In the report, Dorothy has used an ellipse to gate the lymphoctes. The ellipse center did not var very much, as measured by the X and Y geometric means of the cells inside the ellipse. The average ellipse center was located at x-channel 90 and y-channel 62. The ellipse coordinates are (90, 87) for the top, (90, 37) for the bottom, (70, 62) for the left, and (90, 37) for the right. I am currently re-writing the algorithm to use a fixed ellipse for the time being.

For the CD4+ gate, Dorothy used a vertical line at x-channel 64.

I will send you the modified source code for cluster1 for using fixed gates sometime tomorrow I hope.

Sincerely,
Andrea Desrosiers

From: Karl Gu [mailto:kgu@mwi-danam.com]
Sent: Monday, October 16, 2006 12:20 PM
To: Andrea Desrosiers
Subject: RE: PCT Internal Data

Hi Andrea,

In the attached file, how the diff numbers obtained? From EXCELL 22 or other reference machine? Especially could you tell me how the CD4 counts obtained?

Thank you.

Regards,
Karl

From: Andrea Desrosiers [mailto:adesrosiers@pointcare.net]
Sent: Wednesday, September 20, 2006 2:38 PM
To: Karl Gu; Dorothy Branco
Subject: PCT Internal Data

Hello Karl,

Each sample ID (ex. P1009638) will have 4 files associated with it: A and B designate duplicate manual runs using the gold reagent, and -HEM1 and -HEM2 designate duplicate automatic runs using the regular Drew sequence, without gold reagent. We also have data from the 11th through the 15th of September. Please let us know if you wish to have those data files as well. I think

you have plenty of files to work with right now.

Sincerely,
Andrea Desrosiers

EXHIBIT 14

From: Karl Gu
Sent: 10/26/2006 10:34:53 PM
To: Andrea Desrosiers
CC: debarry@pointcare.net
Subject: CD4 algorithm and utility

Hi Andrea,

I delivered the CD4 dll and utility to your ftp server under Drew. Let's say you have a cbc fcs file as in c:\data\100.fcs, the utility will open this file and try to find corresponding cd4 fcs file as c:\data\cd4\100_cd4.fcs. If it exists, it calls cd4 dll to do the calculation and display the cd4 page.

Right now the cd4 dll has only simple cut built in the readresults function, you can plug in what algorithm code as you want. In near future, I plan to add two exported functions to load the cd4 default configuration parameters and a read function which only retrieve calculated results. Then rename the current read function to calculate_new function results.

If you have any questions, please let me know.

Regards,
Karl

EXHIBIT 15

From: Gary Young
Sent: 11/8/2006 10:33:16 PM
To: Andrew Kenney; Andrew Kenney [HOME]
CC:
Subject: Phone call from Don Barry

Andrew,

Don is proposing sending Ami Kaufman, Field Engineer, down the week of the 27th to oversee progress and assist. Her stay would be "for as long as we need her."

He is sending her in his place because his schedule is full in December.

I think it would be a good idea. If we only use her minimally, it may calm Pointcare enough to get them to back off. I sense they are very jittery at the moment.

So much is being said by Frank to Pointcare and by Frank to Doug that I don't feel we are getting the whole story. In other words, POLITICS !

Gary

EXHIBIT 16

From: Gary Young
Sent: 3/20/2007 2:19:49 PM
To: George Chappell; Karl Gu; Jerry West (remote); William Ross; Lee Carter
CC:
Subject: FW: samples from the HT system

From: Amy Coughlin [mailto:acoughlin@pointcare.net]
Sent: Monday, March 19, 2007 9:21 PM
To: Gary Young
Cc: Don Barry
Subject: samples from the HT system

Hi Gary,
Don asked me to pass on a few dot plots that we had gotten recently. As you'll see, the CD4 separation is incredibly amazing, and we're getting really close with tweaking the lysing to get rid of the unlysed RBCs.
I also just wanted to thank you guys again for all the effort you've put into this project. I had a great time working with you all. Thanks for everything!
Amy

Attachment: 579.jpg
Attachment: 582.jpg
Attachment: 591.jpg

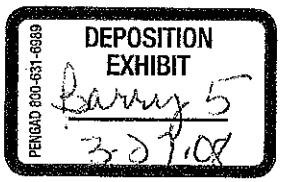


EXHIBIT 17

From: Andrew Kenney
Sent: 3/19/2007 4:10:42 PM
To: peter.hansen@tmo.blackberry.net
CC: Petra Krauledat; Don Barry; Gary Young
Subject: RE: Status summary

Peter

Many thanks for the detailed update. Everyone here is delighted to know that the basic design is sound and working.

We are addressing the gold sensor tube now and have worked out a scheme to replace it with glass.

I think the PCB issue was as a result of being able to apply too much voltage to the sensors. The production boards will have limit resistors.

Your final issue needs more discussion.

Very best regards

Andrew

-----Original Message-----
From: Peter Hansen [mailto:peter.hansen@tmo.blackberry.net]
Sent: 16 March 2007 23:51
To: Andrew Kenney
Cc: Petra Krauledat; Don Barry
Subject: Status summary

Dear Andrew,

Here is a summary (mainl input from Don) of the progress made at Drew by George and Amy, and a a synopsis of the main items to be tackled.

Let me start by saying that we were able to run the system quite a bit before the optical sensor gave a problem. We simply added a few sequence changes that needed oversight from our assay group, and I must say that the CD4 clusters are the best that I have seen on any patform including the one we currently sell. The project definitely is headed to success.

Here is a point by point summary:

* The lyse and quench lines were switched, which caused the large spray of dots (this was a

mistake)
* The flow cell mount was moving around, so the optics needed to be fixed (this too was a mistake)
* There was a problem with the blood sample that was in the exit port of the cuvette. They adjusted the cycle to remove this portion from analysis.
* They had to adjust the sample line so that the leading and trailing edges of the dilution were not counted.
* Numerous adjustments to the lyse and quench mix times and speeds were made to a point where the cycle is almost complete. This may be what got people frustrated. They may have thought that it was necessary to deliver a perfect cycle with no lysing problems. We never thought so. The final tweaking of the lyse step needed PointCare assay people. The delivered machine was very close and only needed a day or two at our end.

Now, what we think is still outstanding…

* The gold optical sensor is giving us problems. We may be able to fix this by using a glass tube. Please note that the Drew team used Lexan, which we tested and told them that it was ok, as long as the machined surfaces are polished. I think the problem lies in that the small channels of the gold channel are virtually impossible to polish and this is creating the buildup. It may also be possible to switch to Delryn, if an infrared sensor can read through it.
* We apparently have a problem with the PCB that the sensors connect to. We would like the team to take a look at it and see if they can find out what went wrong. We are sure this is not a major issue.
* We would like them to take a look at ensuring that we are counting as many cells as possible. We are not sure that we have a problem, but we hope that this doesn't fall off the radar. If the dot plots continue to look as great as they did the other day, we probably will have very high precision with the given hardware and cycle.

Altogether we are very happy at the PointCare end and look forward to moving ahead to field trials.

Peter

Sent wirelessly via BlackBerry from T-Mobile.

EXHIBIT 18

From: Peter Hansen
Sent: 8/2/2007 3:53:46 PM
To: rdipianojr@escalonmed.com; Richard J. DePiano; Doug Nickols; Frank Matuszak
CC: Petra Krauledat; Don Barry
Subject: Update

Gary and George gave Don Barry and me a project update by phone a few days ago. There were two items they reported on.

First, they have isolated the problem with the optics that I had noted to you, and solved it. The heater in the optical head that is there to maintain a constant temperature, was going out of control due to an electrical short. This sent the temperature very high and misaligned the optics. The misalignment "took a set" and did not return to normal when the unit cooled. This explained why we would spend each day aligning the optics, reach perfect alignment (but alignment at an out of control temperature), and then have no alignment the next day when we would start the machine up again. Their solution sounds good to me. We did not discuss this, but I think that one should check to see if this may apply to the 2280 as well.

Second, the optical sensor on the immunogold metering pump is still not functioning satisfactorily even though the changes they have made did help. We conferred and agreed with their suggestion that they abandon optical sensing and try ultrasound. Gary updated us yesterday noting that the ultrasound sensors would not arrive in-house for another two to three weeks. In the meantime they would prepare the mountings for testing.

We have adjusted our schedules accordingly.

We have shipped more immunogold so that they can test the new sensors. We also shipped some good CD4 dot plots that we got during the moments the optics were in alignment, so that Gary would have a goal to hit when they get to testing the new sensors.

Sincerely,

Peter

THERE IS NO EXHIBIT 19

EXHIBIT 20

To: Don Barry
Cc: George Chappell; Karl Gu; William Ross; Doug Nickols
Subject: RE: review meeting

Don,

3:00 PM EDT (2:00PM CDT) is fine.

Thanks,

Gary

From: Don Barry [mailto:debarry@pointcare.net]
Sent: Thursday, May 31, 2007 10:38 AM
To: Gary Young
Cc: William Ross; Amy Coughlin; Peter Hansen
Subject: review meeting

Hi Gary

We would like to have a phone conference on Monday afternoon to review progress made and to discuss what we think we must do for the next steps. Please let me know if 3pm EDT is okay, or if you propose a different time.

Thanks,

Don

From: Peter Hansen
Sent: 6/6/2007 8:01:05 PM
To: Gary Young
CC: Doug Nickols; Amy Coughlin; Don Barry
Subject: Follow up to our phone meeting

Dear Gary,

We are making some progress at this end and would like to get back on the phone this afternoon to discuss a plan. Here is an outline for the discussion. Pardon me for the jargon, but I will refer to the 3 instruments that we have by their local names, "Sam", "Steve", and "George" since they don't have serial numbers.

1. We are of the opinion that there are two sources to our troubles

2. The first is in the fluidics of the CD4 module and the second is in optical alignment of the WA vs SA optics.

3. We were making some decent progress in the fluidics troubleshooting on Sam two weeks ago until the optics clogged or otherwise stoppped working. We know these optics had worked because we got good results with manually prepared samples. It was just a matter of getting the automated CD4 cycle to work.

4. We took the optics out of Steve (this is the instrument on its way back to you), put them in Sam so as to keep going, and ran the following checks.

a. We ran manually prepared samples to be sure the transferred optics were ok, and there we found a problem.

b. The problem is that the "Primary Lymph Gating" clusters (WA vs SA) were very poor.

c. To troubleshoot we ran manual samples on George (the Excell 22 with new optics) and the primary lymph gating clusters were fine. By that I mean there were clear Lym, Mono, and Neut clusters.

d. We ran latex on the two machines (Sam with transferred optics and George) and the latex histograms were identical. Latex in other words was not diagnostic.

e. We then ran Drew lyse and manually prepared samples on Steve and it gave clear Lym, Mono, and Neut clusters on WA vs WA.

5. It may seem strange that the PCT lyse may be sensitive to optical alignment, but it actually is the case, especially when SA scatter is involved.

a. We can reproduce the kind of poor gating clusters we saw by experimenting with our current AuRICA and or a FACScan machine using their respective versions of SA scatter.

6. I propose that we develop an interim optical alignment procedure (or alignment verification procedure) for the primary lymph gating cluster ctytogram (WA vs SA) using manually lysed samples and the PCT lyse. No gold is needed for that.

a. Send you what we think are acceptable clusters to look over.

b. You align the optics in the unit sent to you (Steve with the "cloggeg" optics from Sam) by this procedure.

c. The hurdles are that you will need pipettes, a vortexer with digital speed control (we will send model number)

d. Fresh lyse and quench reagents from us.

7. In the meantime we will, with your phone assistance, try to align the optics that are currently in Sam by the same procedure.

Once we have these optics issues resolved, we will have two things. One will be the basis for an (automated) alignment procedure for WA vs SA that goes beyond latex, and the other is two machines with which we can continue the fluid troubleshooting.

What about 3 PM your time for a phone call?

Peter

EXHIBIT 21

From: Don Barry
Sent: 6/26/2007 12:23:13 PM
To: Gary Young
CC: Doug Nickols; Peter Hansen; Amy Coughlin
Subject: RE: Preliminary Testing of Polyproplyene part

Hi Gary

I need to get some dates from you for delivery of improved modules for the PointCare Complete. This includes the stepper control for the gold mixer, modifications to the gold reservoir, and the material change for the gold sensor. I also need to know a delivery date for the instrument that we had returned to you with these modifications. The system is rapidly nearing the point of system validation and therefore, I must begin to plan our clinical evaluation.

Best Regards,

Don

From: Gary Young [mailto:gyoung@mwi-danam.com]
Sent: Friday, June 22, 2007 7:39 PM
To: Peter Hansen; Don Barry; Amy Coughlin
Cc: Doug Nickols
Subject: Preliminary Testing of Polyproplyene part

Tesing got underway this afternoon for the polpro part. I have nothing conclusive to tell you at this time..

I will e-mail you on Monday as we have more information.

Have a good weekend.

From: Don Barry
Sent: 6/27/2007 12:47:31 PM
To: Gary Young
CC:
Subject: RE: Preliminary Testing of Polyproplyene part

Gary,

Please do not placate me with blanket statements about quality. We are not just a customer, but also a development partner who will work with you to ensure that the highest quality product is designed. I understand that these items were not fully tested in the previous revisions at Drew and thus have created a concern regarding the quality of deliverables. However, you must understand that to effectively manage the project, we must work to a timeline for all project items. Let's see if I can help…

Stepper motor control for gold mixer:

You state that this item is working flawlessly, so I must assume that the hardware modification is complete and the service software has been modified. As I understand it, this item is complete and you could send the hardware and software modifications to us at any time.

Modifications to the gold reservoir:

The schedule can be broken up into 3 parts—date for the part to be manufactured by your shop, timeframe and protocol for testing the part (how do you know when you are "done"), and date for delivery of the part to PointCare. Please include in the testing procedure the actual operation by a customer—specifically, using the pipette to transfer the gold into the reservoir and evaluate ergonomics.

Gold sensor:

As of now, you have 24 samples without a reduction in voltage with the gold sensor. You state that testing is not complete—what is your endpoint? Have you set a specific number of sample or days? Have you set a specification for allowable voltage drop within those numbers of samples, days, or combination of both?

It appears that the reason you cannot give me a timeframe for completion is that you do not have a clear testing protocol. If you clearly define your endpoint, I believe that a schedule will fall into place. We are certainly available to provide assistance, if necessary.

Best regards,

Don

From: Gary Young [mailto:gyoung@mwi-danam.com]
Sent: Tuesday, June 26, 2007 7:30 PM
To: Don Barry
Cc: Doug Nickols; Peter Hansen; Amy Coughlin; George Chappell; William Ross; Jerry West (remote)
Subject: RE: Preliminary Testing of Polyproplyene part

Don,

Testing on the Polyproplyene corner is progressing but at a slower pace than expected. We've had two significant delays consisting of debris in the system and an issue with the optic head. The debris we can explain but the optichead issue was with the power level setting of the laser diode.

We've now run approx. 24 samples using the gold and have seen no reduction in voltage coming from the optical sensor. This is a good sign but much too early to be conclusive. We will continue runnuing samples on Wednesday.

We are having two new gold reservoirs made from Polyproplyene and Teflon to alleviate the staining issues we are seeing with the gold in the Acetal material.

The new mixing stepper motor design is working flawlessly. When the testing of the remaining subsystems is completed, we will want to exchange the unit with the one you currently have and bring it up to the same revision level.

The delivery dates of the modules and Instrument are directly related. Until we are satisfied they are are working properly, we will not ship it to you.

PLEASE UNDERSTAND, OUR REPUTATION FOR BUILDING A QUALITY PRODUCT, THAT MEETS YOUR DEMANDS, IS AT STAKE. WE ARE TAKING EVERY STEP POSSIBLE TO INSURE YOU ARE SATISIFIED WITH THE PRODUCT WHEN IT IS DELIVERED.

Regards,

Gary Young

From: Don Barry [mailto:debarry@pointcare.net]
Sent: Tuesday, June 26, 2007 7:23 AM
To: Gary Young
Cc: Doug Nickols; Peter Hansen; Amy Coughlin
Subject: RE: Preliminary Testing of Polyproplyene part

Hi Gary

I need to get some dates from you for delivery of improved modules for the PointCare Complete. This includes the stepper control for the gold mixer, modifications to the gold reservoir, and the material change for the gold sensor. I also need to know a delivery date for the instrument that we had returned to you with these modifications. The system is rapidly nearing the point of system validation and therefore, I must begin to plan our clinical evaluation.

Best Regards,

Don

From: Gary Young [mailto:gyoung@mwi-danam.com]
Sent: Friday, June 22, 2007 7:39 PM
To: Peter Hansen; Don Barry; Amy Coughlin
Cc: Doug Nickols
Subject: Preliminary Testing of Polyproplyene part

Tesing got underway this afternoon for the polpro part. I have nothing conclusive to tell you at this time..

I will e-mail you on Monday as we have more information.

Have a good weekend.

Gary

EXHIBIT 22

From: Gary Young
Sent: 9/13/2007 4:48:31 PM
To: Peter Hansen
CC: Don Barry; Doug Nickols; Frank Matuszak; George Chappell; Richard J. DePiano
Subject: RE: Progress?

Peter,

I did not receive the e-mail regarding the Barbados conference. Please resend it.

We received two of the ultrasonic sensors and installed one on the PointCare unit. It works very well. Due to it's large size, we could not mount it in the exact same location as the optical sensor. This required some modification to the decks to get the gold reagent consumption back to 20 microliters.

George made some other modifications to the decks to reduce some carryover following the gold injection sequence.

We are in process of testing a bimetal switch in the optichead heater system, as a failsafe, to guard against overheating. The testing on this has just started. We feel some of the optichead problems may have been caused by overheating.

The separation of the CD4 cluster looks good using the automatic mode.I will send you several FCS files following this e-mail.

We are confident the unit is working as expected and are ready to ship it back to you on Septemb er 18th without the bimetal switch installed.
George thinks another week is needed to verify it is working properly.

If that is acceptable, please let me know and we will dust off the shipping box.

Regards,

Gary Young
Drew Scientific, Inc.

From: Peter Hansen [mailto:phansen@pointcaretechnologies.com]
Sent: Thursday, September 13, 2007 10:25 AM
To: Gary Young
Cc: Don Barry; Doug Nickols
Subject: Progress?

Gary,

I haven't heard anything from you since the first of August when you thought that you would have ultrasonic gold sensors to test in two to three weeks. As I said in my email to you a couple of weeks ago, there was a lot of interest in the machine at the Barbados conference. Did you get the email, because I still didn't hear anything back? Anyway, I am genuinely interested in what's happening and what we can do to help. I am not a marketing guy, but I think from what I see in the field, the system has a future.

Peter

EXHIBIT 23

From: Peter Hansen
Sent: 7/2/2007 7:54:19 PM
To: Richard J. DePiano
CC: Frank Matuszak; Doug Nickols; Sam Hill; Petra Krauledat; Don Barry; Linsey Rockingham
Subject:

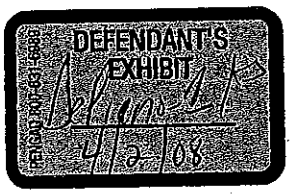
Dear Richard;

I am concerned about the lack of engineering progress on the 2280/CD4 (PointCare Complete) during 2007. At this time we have no working instruments from Texas despite having demonstrated that the assay worked satisfactorily in a preliminary trial (Barbados) in late in 2006.

The schedule called for Texas engineering to automate the assay over the winter and spring months of 2007. When they had failed to get a system working by March and we found there were no microscopes or other biological troubleshooting tools available at the Texas site to diagnose the situation (very unusual for a hematology company), we moved two instruments to Massachusetts to help locate and identify the problem(s). This was not a welcome undertaking at PointCare because, with the Drew schedule slippage, the 2280/CD4 project was on a direct collision with the PointCare NOW project schedule.

By June, PointCare had located the main problem responsible for blocking all progress. It turned out to be malfunctioning optics. This was a major surprise since the optics Drew supplied for the 2006 Barbados trial had worked well. Once on this trail we found that of the several optical heads Drew had built, the majority were malfunctioning. Once a Drew test technician "fixed" the optics at PointCare we were able three weeks ago to identify the rest of the engineering areas that needed work in Texas. The main item that needed to be fixed was the gold optical sensor material which became coated with gold and rendered useless. We have experience in this area and sent two materials suggestions to Texas. Additionally, the Luer assembly for injecting gold into the reservoir exhibited backpressure and did not work. We sent a design modification to Texas. We asked for an improved motor speed control on a mixer motor, and this has been constructed but not tested.

I am losing confidence in the Drew aspects of this project because:



1. Drew engineering has not delivered working instruments.

2. Problem discovery and resolution has been driven from PointCare. There is no engineering management in place in Texas. I get temporary action when I talk to Jerry West or Frank Matuszak, but their roles are clearly unofficial and focused on the specific problem that I identify. While helpful, they are not substitute managers.

3. PointCare pinpointed the optics as the problem, but we have no information as to what the problem really was. The majority of optical heads that we have tested did not work and I am not comfortable that because the Drew test technician could fix the heads, we should be confident that there is an engineering solution in place.

4. Because of the delay caused by optics, the serious work on the fluidics is still in an early stage.

5. We have no response when we asked for a formal timeline revision estimate from Texas engineering. The responses from Gary Young are a piecemeal overlay of "fixes". He sends parts for us to install and try out at PointCare, but I am looking for complete and tested systems.

6. The engineering phase of the project is months off schedule, has no corrective action plan, and needs Drew management review.

As a consequence of the above, PointCare will not commit to a date or proceed with the clinical studies of the system until three identical units are constructed by Drew, tested for engineering reliability by Drew, shipped to Massachusetts, installed by Drew, and satisfactorily validated by PointCare on patient samples. I am putting the clinical phase of the project on hold at PointCare until I see that all performance specifications in our contract are met consistently by three units. Right now, I do not have confidence that Drew can actually manufacture the system reliably.

Please let me know the plans for timeline revision and delivery of working systems.

Sincerely,

Peter Hansen

Chief Scientific Officer

PointCare Technologies, Inc

W. Peter Hansen, PhD
Chief Scientific Officer
PointCare Technologies, Inc.

EXHIBIT 24

From: Richard J. DePiano Jr.
Sent: 7/13/2007 9:19:14 PM
To: phansen@pointcare.net
CC: Richard J. DePiano
Subject: Drew - PointCare

Dear Peter:

Your correspondence of July 2 was referred to me for follow-up investigation and reply.

Needless to say, we at Drew value the relationship that we have with you, Petra and PointCare. To this end, we have promptly and critically evaluated the concerns that you noted in your correspondence.

While I do not believe that it would prove productive to respond point-by-point to all of your assertions, I will attempt below to provide you with our overall assessment, as well as more detailed feedback on some of the more material assertions.

It is my impression that your concerns center primarily upon the ability of Drew's AuRica HT instrument to properly perform in a commercial setting. You have expressed reservations that the two instruments that you have worked with did not perform satisfactorily, that Drew's engineering capabilities are limited, and that communications from Drew relative to project timelines and status have not been satisfactory from your perspective.

As you know, Drew was reluctant to ship the two AuRica HT machines to PointCare and had requested that PointCare have its expert work on the assay mixing component at Drew's Dallas facility so that Drew's engineers would be readily available to assist. As you also know, you personally demanded that the instruments be shipped to PointCare. It remains the position of Drew that the two AuRica HT instruments, including the optics components, were fully operational (less the PointCare assay mixing) and in good working condition when shipped.

Unfortunately and without consulting Drew, PointCare unilaterally decided to have its personnel disassemble both instruments once they arrived at PointCare so that PointCare's team could work

on Assay Mixture Component development. This occurred without a Drew engineer present and despite our specific guidance to the contrary. During the process, PointCare personnel damaged and misaligned key components of the AuRica HT equipment.

While you are correct that PointCare's assay appeared to work in a preliminary trial, you fail to mention that the automated mixing method was built per specifications provided by PointCare. While you complain that the optics provided by Drew malfunctioned when automated mixing was undertaken, you fail to note that the problems encountered as we moved to the automated mixing method were primarily related to PointCare's gold attaching to the surface of the optics (which was of a base material specified precisely by PointCare). As you may recall, Drew had specifically recommended against the use of this surface composite and had proposed an alternative material, which was rejected by PointCare. Further, despite PointCare's assertions that the optic problems being encountered during the automated mixing phase were not related to its choice of surface composite or its gold optical sensor material, this proved to be exactly the case. Drew's engineer confirmed that this was the true root cause and then was able to effectuate an appropriate modification. PointCare's delay in acknowledging this fact (as you may remember, PointCare initially dismissed the possibility that its gold was attaching to the surface of the optical sensor) resulted in further project delay.

Of equal concern to Drew from a "time lost" perspective is the fact that when PointCare did return one of the instruments to Drew's Dallas facility, it experienced material damage that Drew had to repair because PointCare had failed to properly drain the assay fluids from the equipment prior to shipping.

Peter, the above is not meant to be a rebuttal nor to be accusatory/"finger-pointing". My feedback, however, is intended to underscore that the problems you identify are not necessarily wholly of Drew's making. Drew has and will continue to work diligently to meet its contractual obligations to PointCare. In the same spirit, Drew expects PointCare to do the same. I firmly believe that what is needed at this juncture is an open dialogue, a continued spirit of cooperation, and an agreed upon strategic plan that takes into consideration our current status so that we expeditiously move forward to achieve our mutual goals.

As I understand, Drew agreed to deliver two (2) operational AuRica HT instruments to PointCare. Drew did in fact meet its obligation. PointCare subsequently provided Drew with change orders that requested material specification modifications to the AuRica HT. Drew has completed most of PointCare's requested changes and is presently working through the remaining change order modifications requested by PointCare. Just as Drew has previously and continues to

meet its obligations, it expects that PointCare will honor its obligation and promptly proceed with clinical studies.

If you desire a further discussion of the above, please give me a call. Otherwise, please confirm that PointCare will proceed with its obligations as defined by our Agreement.

Thank you and regards,

Rich, Jr.

ESCALON MEDICAL CORP

By: Richard J. DePiano, Jr., Esquire

Chief Operating Officer & General Counsel

565 East Swedesford Road

Suite 200

Wayne, PA 19087

610 254-8930 Direct Telephone

610 688-5278 Direct Fax

610 688-6830, Extension 103

EXHIBIT 25

EXHIBIT U

DuaneMorris

ANTHONY J. COSTANTINI
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PERSONAL FAX: 212.692.1020
E-FAX: 212 202-4715
E-MAIL: ajcostantini@duanemorris.com

www.duanemorris.com

January 24, 2008

VIA FEDERAL EXPRESS
AND E-MAIL
Normand F. Smith, Esq.
Burns & Levinson
125 Summer Street
Boston, MA 02110

Re: PointCare Technologies, Inc.

Dear Mr. Smith:

I was somewhat surprised by the content your letter of January 22, since it is clear that there has been some miscommunication. We have never refused to turn over any HT information, but have only said that we have no legal obligation to do so. Under the Agreement, we can simply send the HT instrument itself. Further, we have said that we were willing to provide access to the data voluntarily if you were willing to accept our conditions on the shipment of the equipment, and I frankly don't know how my last letter could have been clearer on this point. Now that you have belatedly confirmed your acceptance, Dr. Chow's report, which reflects the data he relied upon, is enclosed. Now, we will see about PointCare's good faith.

With respect to Dr. Chow, I have made clear that our position is that a collective telephone conference after your client reviews his report is useful, if not necessary, to understanding the data. If, as we suspect, your client agrees after reviewing the report, despite your earlier protestations to the contrary, we will make the necessary arrangements upon request. Dr. Chow is generally available for such a consultation for the next several days, but you should let me know at once.

We also have no doubt as to the necessity of testing the device, and we would like to make the necessary shipping arrangement as soon as possible - - an offer that we made almost six weeks ago and, unfortunately, not accepted upon our conditions until your last letter. We will need a few days' advance notice, but no more.

DuaneMorris

Normand F. Smith, Esq.
January 24, 2008

We also think the time is ripe to discontinue the nonsense about our NP machine. Please return this machine as soon as the review of the data is complete. In addition, we have learned (from the FDA website) that the FDA has approved the NP unit, based at least in part on data generated by a Drew system on loan to PointCare. We are pleased with this result. I believe your client already has an existing Purchase Order (Drew Purchase Order 23260), which we now expect to be filled.

Very truly yours,

Anthony J. Costantini

AJC/gg

cc: Richard J. DePiano, Sr.
Petra Krauledat

Rubicon Consulting

Confidential

Technical Report

Verification of POINTCARE CD4sure Test On Drew HT Instrument

Rev: 3.0

Approved and Issued By:

Rubicon Consulting
General Manager: Herbert Chow

Release Date: Dec 11, 2007

Rubicon Consulting
Confidential

Technical Report

Verification of POINTCARE CD4sure Test
On Drew HT Instrument

Rev: 3.0

Approved and Issued By:

Rubicon Consulting
General Manager: Herbert Chow

Rubicon Consulting

Confidential

Rubicon Consulting

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1. Purpose:

This report is being written to summarize the findings from the testing of the PointCare CD4sure assay kit on the DREW HT instrument (HT). Work was performed from Nov 27 to 28, 2007 at Drew Scientific in Dallas, Texas.

2. Scope:

Data obtained from this study are used to verify the performance of HT against the established system specifications. The design of experiment in this summary applies to the Verification Test Matrix (Appendix A) in the document titled "PointCare CD4sure Verification V1.0.0 Procedure". The Method column indicates if the specific requirement is included ("tested" or "observed") or excluded ("not tested") from this study. Specifications not included in this study were summarized in Appendix A of this document

- This study was designed and data analyzed by Rubicon's personnel ("RB")
- Fresh EDTA blood specimens were collected on site.
- Blood specimens were handled and prepared by RB
- Operation of the HT was handled by William Ross (Drew Scientific)
- Operation of the Excell 2280 was handled by personnel in Drew's QC laboratory
- All off-line analyses of CD4 were done by William Ross using a third party FCS Software with data obtained from HT

3. Reference:

- Attachment 3 to Annex 1 titled "Synopsis of PointCare Technologies Assay for the Identification of CD4 Positive Lymphocytes: Expression as Percentage of Lymphocyte Count ("CD4%") and CD4 Lymphocyte Count ("CD4 Absolute")
- Attachment 2 to Annex 1 titled "Product Specifications for HT Instrument"
- PointCare CD4sure Verification V1.0.0 Procedure

4. Equipment and Materials:

4.1. PointCare Aurica HT Instrument Information

- Analyzer Serial Number HT70002
- Mfg Date: May 7, 2007

4.2. CD4 Immunolabeling reagents

- PointCare CD4HT Gold Reagent Lot#G73560
- PointCare ACCEL Lot #HTL8185
- PointCare Reconstitution Lot #R818805

4.3. Coulter reagents

- Coulter Scatter PAK P/N 8546917
- Erythrolyse II &Stabilyse Lot#110857K 2007-11-16 Exp Date

(Although reagent was two weeks passed expiration, test result comparisons between reference and HT showed no statistical significant differences)

4.4. Drew reagents

- Drew Diluent RA-1720 Lot#3014
- Drew Clean RA-004C Lot#3201
- Drew Shealth RA-6010 Lot#3088
- Drew Lyse RA-9500 Lot#3055

4.5. R&D System - CD4 Controls

- CD4 Normal Control FC127Normal Exp date 1/2/2008
- CD4 Low Control FC127 Low Exp date 11/2/2007

5. Experiment Design:

5.1. Blood specimen preparation

5.1.1. 30 mL of blood from a single donor was distributed into 8 purple top vacutainer tubes.
5.1.2. Tube #1 and 2 were labeled as "Normal".
5.1.3. Tube #3, 4 and 5 were centrifuged in a fixed rotor centrifuge (1700 RPM) for 15 minutes. Eight hundred mircro-liter (800 uL) of buffy-coat cells were collected (totaled 2400 uL) in a clean 5 mL glass tube.
5.1.4. Cells in Tube #3, 4 and 5 were pooled, remixed, redistributed in the same tubes and labeled as "Low".
5.1.5. The isolated buffy-coat cells were mixed with blood tubes #6, 7 and 8. The tubes were labeled as "High".
5.1.6. Baseline CBC data were established both on the HT and Excell2280.

6. Summary:

Although this study included limited observations utilizing only a handful of contrived blood specimens, several trends have evolved from the data set.

- Absolute WBC and lymphocyte counts obtained from the HT correlated highly (r2 for WBC = 0.997; r2 for Lymphocyte = 0.987) with those from the reference Excell 2280.
- At least with the low CD4 control from R&D System, HT correctly reported control values for lymphocyte counts, CD4 Absolute and CD4%.
- HT does not yet have the algorithm to report correct CD4 Absolute and CD4%. However, meaningful CD4 results had be generated using data set obtained from HT with a third party FCS software. Proper gating of CD4 positive events within the lymphocyte population coupled with the absolute lymphocyte counts have produced reproducible CD4 results.
- HT passed all system specifications identified in the verification procedure.

7. Results and Discussion:

Detailed raw data and calculations can be found in the following documents:

- Raw data file: Excell24 (MDB file)
- Raw data file on CD4 analysis using FCS Software (PDF files)
- Raw data and calculation: Drew-Pointcare Verification 071130 (Excel file)

7.1. Observed items

Requirements	Specifications	Observed Results
PR-008-022a	[Autoloader handling] Accommodate standard 5 mL vacutainers	**Passed** All 80+ runs in the study were carried out in standard purple top 5 mL EDTA tubes. HT autoloader was able to handle all runs.
PR-008-021	[Autoloader Throughput] Autoloader works for 1 hour or processes 30 specimens unattended	**Passed** The autoloader ran over 80 runs in two consecutive days without a hitch. There were no interventions other than loading, unloading of tubes and managing worklist.
PR-008-026	[Autoloader: cap piercing] Cap piercing capability	**Passed** All 80+ runs in the study were carried out in closed EDTA tubes using the cap piercing function.
PR-008-036	[Controls] Control materials for CD4 Absolute and CD4% in capped tubes with barcodes	**Passed** High and low CD4 controls were supplied in capped tubes and by R&D System.
PR-008-024	[System: 5 pt WBC Diff + CD4] 1st pass – WBC Diff without immunogold 2nd pass – CD4% with immunogold	**Passed**
PR-008-0052	[System: CD4 reagent] Lyophilized or desiccated bulk gold reagent easily reconstituted by unskilled technician	**Passed** Since precision pipetting is not required in the transfer of diluent to the lyophilized gold reagent, the procedure should be able to handle by an unskilled tech. **Observation:** Seven CD4HT vials were

		inspected. Inconsistent fill volume was observed in 3 of 8 vials. Seven of the vials were shown in Appendix B. Four vials with similar fill volume were used in the current study.

7.2. System Throughput

Requirements	Specifications	Results
PR-008-020	[System Throughput] 4.5 (4:30) minutes per specimen	**Passed** As shown in Table 1, elapsed time between consecutive runs of CBC+CD4 ranging from 4:19 to 4:21 minutes

Table 1 CDB+CD4 elapsed time between runs

	Normal #1		Time elapsed (min)	WBC	Neut	Lymp	Mono	CD4 (HT)
2083	11/28/2007	1:01:32 PM		5.4	2.8	1.8	0.7	717.7
2084	11/28/2007	1:05:52 PM	0:04:20	5.6	2.9	1.9	0.7	728
2085	11/28/2007	1:10:12 PM	0:04:20	5.5	3	1.8	0.6	702.4
2086	11/28/2007	1:14:32 PM	0:04:20	5.5	3	1.8	0.6	722.2
2087	11/28/2007	1:18:52 PM	0:04:20	5.6	2.9	1.9	0.7	767.3
2088	11/28/2007	1:23:12 PM	0:04:20	5.5	2.9	1.9	0.6	756.7
2089	11/28/2007	1:27:32 PM	0:04:20	5.5	2.9	1.9	0.6	748.8
2090	11/28/2007	1:31:52 PM	0:04:20	5.3	2.8	1.8	0.6	732.5
2091	11/28/2007	1:36:12 PM	0:04:20	5.3	2.8	1.8	0.6	724.1
		Range	4:20					
	Normal #2							
2133	11/29/2007	12:47:04 PM		7.70	4.60	2.10	0.80	800.60
2134	11/29/2007	12:51:23 PM	0:04:19	7.80	4.60	2.10	0.80	815.70
2135	11/29/2007	12:55:43 PM	0:04:20	7.70	4.60	2.10	0.80	853.40
2136	11/29/2007	1:00:02 PM	0:04:19	7.70	4.60	2.10	0.80	828.80
2137	11/29/2007	1:04:22 PM	0:04:20	7.40	4.40	2.00	0.70	802.30
2138	11/29/2007	1:08:42 PM	0:04:20	7.40	4.50	2.00	0.70	808.70
2139	11/29/2007	1:13:01 PM	0:04:19	7.50	4.60	2.00	0.70	798.40
2140	11/29/2007	1:17:22 PM	0:04:21	7.60	4.50	2.00	0.80	767.50
		Range	4:19 to 4:21					

7.3. Precision

7.3.1. Precision - WBC

Requirements	Specifications	Results
PR-008-006	[Precision of WBC] <2% at WBC counts of 8000/uL	**Passed** As shown in Table 2, in three separate specimens: • CV of <1% was observed with WBC at 15,400/uL • CV of 2.18% was observed with WBC at 8,680/uL • CV of 1.99% was observed with WBC at 7,600/uL • CV of 1.91% was observed with WBC at 2,425/uL
PR-008-009	[Precision of Neutrophil] CV% <60% [4,800/uL] is <3% at WBC count >8000/uL	**Passed** As shown in Table 2, in three separate specimens: • CV of 1.59% was observed with Neutrophil at 9,190/uL • CV of 4.23% was observed with Neutrophil at 4,480/uL • CV of 1.66% was observed with Neutrophil at 4,550/uL
PR-008-007	[Precision of Lymph] <3% at Lymphocyte counts of 2000/uL	**Passed** • CV of 1.75% was observed with Lymph at 4,330/uL • CV of 1.96% was observed with Lymph at 2,050/uL • CV of 0.0% was observed with Lymph at 800/uL

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Table 2 Precision of WBC, Lymph and Neutrophil

		WBC	Neut	Lymp
High	12:03:38 PM	15.30	9.00	4.40
High	12:07:58 PM	15.30	9.20	4.30
High	12:12:18 PM	15.60	9.30	4.40
High	12:16:39 PM	15.40	9.00	4.30
High	12:20:59 PM	15.20	9.20	4.20
High	12:25:19 PM	15.40	9.20	4.30
High	12:29:39 PM	15.60	9.40	4.40
	Mean	15.40	9.19	4.33
	Std Dev	0.15	0.15	0.08
	CV%	0.99%	1.59%	1.75%
High	11:59:02 AM	8.7	4.6	2.9
High	12:03:22 PM	8.8	4.5	3
High	12:07:42 PM	8.8	4.6	3
High	2:26:54 PM	8.4	4.2	2.9
	Mean	8.68	4.48	2.95
	Std Dev	0.19	0.19	0.06
	CV%	2.18%	4.23%	1.96%
Normal	12:47:04 PM	7.70	4.60	2.10
Normal	12:51:23 PM	7.80	4.60	2.10
Normal	12:55:43 PM	7.70	4.60	2.10
Normal	1:00:02 PM	7.70	4.60	2.10
Normal	1:04:22 PM	7.40	4.40	2.00
Normal	1:08:42 PM	7.40	4.50	2.00
Normal	1:13:01 PM	7.50	4.60	2.00
Normal	1:17:22 PM	7.60	4.50	2.00
	Mean	7.6	4.55	2.05
	Std Dev	0.15	0.08	0.05
	CV%	1.99%	1.66%	2.61%
Low 2	1:55:58 PM	2.4	1.3	0.8
Low 2	1:55:58 PM	2.4	1.3	0.8
Low 2	2:00:17 PM	2.4	1.2	0.8
Low 2	2:00:17 PM	2.4	1.2	0.8
Low 2	2:04:37 PM	2.4	1.4	0.8
Low 2	2:04:37 PM	2.4	1.4	0.8
Low 2	2:13:56 PM	2.5	1.4	0.8
Low 2	2:13:56 PM	2.5	1.4	0.8
	Mean	2.425	1.325	0.8
	Std Dev	0.05	0.09	0.00
	CV%	1.91%	6.69%	0.00%

7.3.2. CD4 Precision

HT excludes monocyte and counts only lymphocytes within the lymphocyte gate. Although HT is capable of reporting CD4% and CD4 Absolute, these numbers are not reliable since CD4 algorithms have not been implemented. An off-line FCS Software is used to provide proper gating of the CD4+ events within the lymphocyte population. It estimates the percentage of CD4 positive events within the lymphocyte gate. CD4 counts are obtained by manually multiplying the CD4 percentage with the lymphocyte counts from impedance.

PR-008-003	[Precision CD4 count] A maximum of ±25/uL (12.5%) at CD4 counts of 200/uL	**Not tested but partially passed; final algorithm is not available** The observed CVs were well below the 12.5% (25/uL at 200/uL) sepecification. As shown in Table 3: • CV of 9.04% was observed with CD4 counts about 119/uL • CV of 5.48% was observed with CD4 counts about 354/uL

Table 3 Precision of CD4 counts

			WBC (000)	Lymp (000)	Total lymph	CD4+ events	CD4% (FCS)	CD4 (FCS)
2093	11/28/2007	1:55:58 PM	2.4	0.8	1049	468	44.61%	356.91
2093	11/28/2007	1:55:58 PM	2.4	0.8	1049	468	44.61%	356.91
2094	11/28/2007	2:00:17 PM	2.4	0.8	1080	515	47.69%	381.48
2094	11/28/2007	2:00:17 PM	2.4	0.8	1080	515	47.69%	381.48
2095	11/28/2007	2:04:37 PM	2.4	0.8	1064	441	41.45%	331.58
2095	11/28/2007	2:04:37 PM	2.4	0.8	1064	441	41.45%	331.58
2096	11/28/2007	2:13:56 PM	2.5	0.8	1052	456	43.35%	346.77
2096	11/28/2007	2:13:56 PM	2.5	0.8	1052	456	43.35%	346.77
		Mean						354.18
		Std Dev						19.41
		CV%						5.48%
2114	11/29/2007	11:24:42 AM	1.70	0.40	215.00	58.00	26.98%	107.91
2115	11/29/2007	11:29:02 AM	1.70	0.40	214.00	59.00	27.57%	110.28
2116	11/29/2007	11:33:22 AM	1.80	0.40	303.00	96.00	31.68%	126.73
2117	11/29/2007	11:37:41 AM	1.80	0.40	365.00	106.00	29.04%	116.16
2118	11/29/2007	11:42:01 AM	1.80	0.40	319.00	91.00	28.53%	114.11
2119	11/29/2007	11:46:20 AM	1.70	0.30	230.00	87.00	37.83%	113.48
2120	11/29/2007	11:50:39 AM	1.70	0.40	333.00	94.00	28.23%	112.91
2121	11/29/2007	11:54:58 AM	1.70	0.40	280.00	98.00	35.00%	140.00
2122	11/29/2007	11:59:18 AM	1.70	0.40	313.00	102.00	32.59%	130.36
		Mean						119.10
		Std Dev						10.77
		CV%						9.04%

PR-008-004	[Precision of CD4%] For Lymph at 1500/uL, CD4 precision ±2%	**Not tested; final algorithm is not available**
PR-008-005	[Precision of CD4%] CD4 monocytes excluded from analysis	**Passed**
PR-008-003	[Reportable Range CD4] From 50 to 6000/uL	**Not tested**

7.3.3. CD4 Counts

Although a crude CD4 algorithm is used in the current HT software, the CD4 counts reported by the HT were significantly different but not too far off with those obtained from the FCS program (see Table 4). In fact, at higher CD4 levels, the HT algorithm yielded a tighter CV.

Table 4 CD4 counts and percent comparison between HT and FCS analysis

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		HT		FCS	
Runs	Date	Mean	CV%	Mean	CV%
2123-2129	11/29/2007	1522.39	3.50%	1785.70	5.55%
2075-2099	11/28/2007	1298.00	3.01%	1227.66	8.44%
2133-2140	11/29/2007	809.425	3.08%	839.65	3.42%
2078-2091	11/28/2007	751.24	4.50%	735.35	6.85%
2072-2074	11/28/2007	417.83	6.94%	287.10	12.75%
2093-2096	11/28/2007	436.4	5.80%	354.18	5.48%
2114-2122	11/29/2007	165.10	23.35%	119.10	9.04%

7.4. Heating requirement for CD4 counts

PR-008-043c	[System: reagent] Heater will be needed for gold reagent	**Passed** Heating is essential to get consistent CD4 counts and percent. As shown in Table 5: • CD4 counts of specimen #1 had an elevated CV% of 20% at 25C vs. 9% at 37C • CD4 counts of specimen #2 had an elevated CV% of 44% at 25C vs. 7% at 37C

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Table 5 Precision of CD4 counts at 25°C vs. 37°C

					WBC	CD4	CD4% (FCS)	CD4 count (FCS)
	Specimen #1							
2062	High	25C	11/28/2007	10:46:34 AM	8.1	452	21.89%	613
2066	High	25C	11/28/2007	11:11:51 AM	8.6	945	30.20%	906
2067	High	25C	11/28/2007	11:16:11 AM	8.7	1052	32.81%	984
2068	High	25C	11/28/2007	11:20:31 AM	8.8	1039	31.71%	951
				Mean				864
				Std Dev				170
				CV%				20%
2075	High	37C	11/28/2007	11:59:02 AM	8.7	1239	37.27%	1081
2076	High	37C	11/28/2007	12:03:22 PM	8.8	1286	40.94%	1228
2077	High	37C	11/28/2007	12:07:42 PM	8.8	1220	43.49%	1305
				Mean				1205
				Std Dev				114
				CV%				9%
	Specimen #2				WBC	CD4	CD4%	CD4 count
2069	Normal	25C	11/28/2007	11:24:51 AM	5.7	526	29.40%	559
2070	Normal	25C	11/28/2007	11:29:10 AM	5.6	547	29.74%	208
2071	Normal	25C	11/28/2007	11:33:30 AM	5.8	447	25.33%	481
				Mean				416
				Std Dev				184
				CV%				44%
2078	Normal	37C	11/28/2007	12:12:02 PM	5.5	858	40.07%	721
2079	Normal	37C	11/28/2007	12:16:21 PM	5.6	851	35.22%	669
2080	Normal	37C	11/28/2007	12:20:41 PM	5.6	887	36.35%	654
2082	Normal	37C	11/28/2007	12:57:15 PM	5.2	789	39.33%	669
2083	Normal	37C	11/28/2007	1:01:32 PM	5.4	859	40.05%	721
2084	Normal	37C	11/28/2007	1:05:52 PM	5.6	759	40.92%	777
2085	Normal	37C	11/28/2007	1:10:12 PM	5.5	786	40.33%	726
2086	Normal	37C	11/28/2007	1:14:32 PM	5.5	955	45.39%	817
2087	Normal	37C	11/28/2007	1:18:52 PM	5.6	815	41.35%	786
2088	Normal	37C	11/28/2007	1:23:12 PM	5.5	632	38.56%	733
2089	Normal	37C	11/28/2007	1:27:32 PM	5.5	859	41.66%	792
2090	Normal	37C	11/28/2007	1:31:52 PM	5.3	836	41.97%	755
2091	Normal	37C	11/28/2007	1:36:12 PM	5.3	814	41.09%	740
				Mean				735
				Std Dev				50
				CV%				7%

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7.5. Specimen stability

PR-008-017	[Specimen Age CD4 counts and %] Sample age up to 8 hrs	**Passed** As shown in Figure 1-3: • Stable CBC parameters were observed up to 5-6 hours post blood collection in EDTA

Figure 1

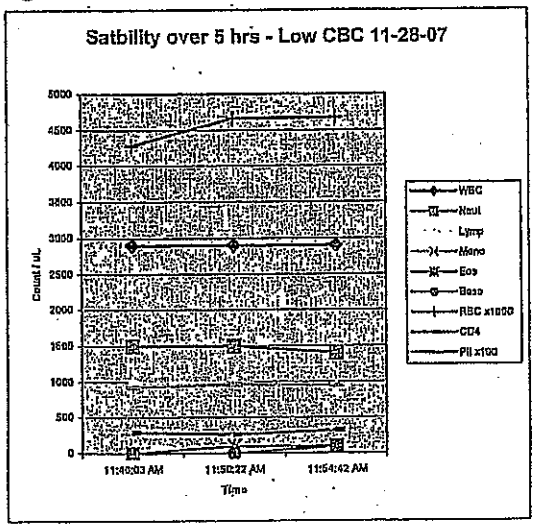
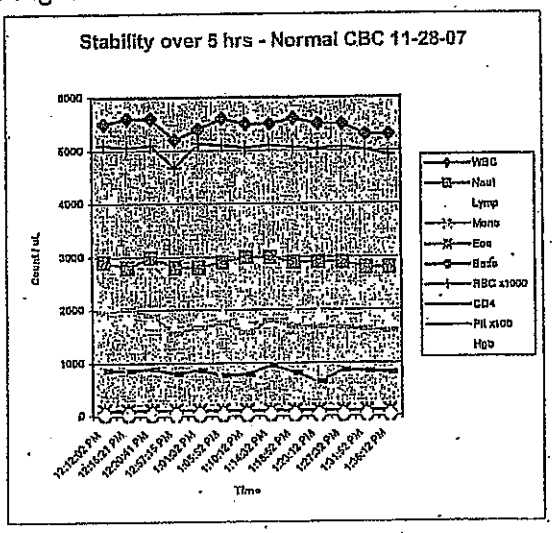


Figure 2



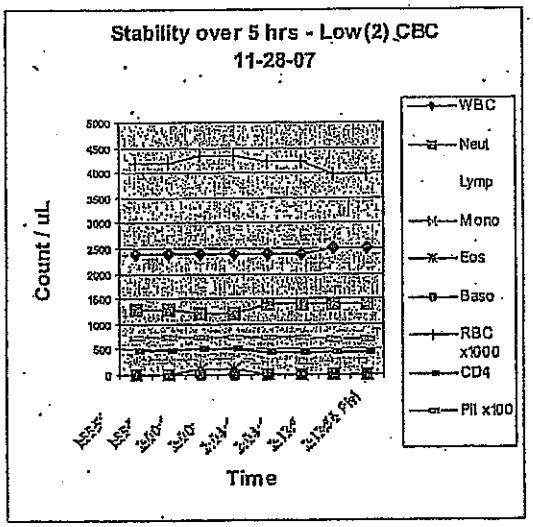


Figure 3

7.6. Accuracy

7.6.1. R&D high and low control

CD4 low and normal controls were purchased from R&D System. The expected performance was listed in the following table.

R&D System	FC127 Low	FC127 Normal
Exp	11/2/2007	1/2/2008
WBC	3781 ul	3982
Lymphocyte	757	851
Lymph %	20	21.4
CD4%	8.1 (4.1 to 12.1)	50.6 (44.1 to 57.1)
CD4 counts	61.3 (30.7-92)	430.6 (323-538.3)
	Low control	Normal control

Table 4 summaries the performance of R&D System's normal and low CD4 controls on HT. For the low CD4 control, all perimeters including WBC, Lymphocyte counts, CD4 percentage and CD4 counts were within expected ranges published by R&D System. For the normal CD4 control, HT had a high bias on lymphocyte counts, CD4 counts and a low bias on CD4 percentage. The inaccuracy results could be attributed to the fact that correct CD4 instrument calibration factors have not been installed on the system. Systematic studies of these and other CD4 control materials across multiple HT instruments will be necessary to obtain statistically significant values for these correction factors.

Table 3 Performance of R&D System CD4 controls on HT

				WBC (x1000)	Lymp (x1000)	Lymph (FCS)	CD4 (FCS)	CD4% FCS	CD4 count FCS	Range
	FC127 Low CD4									
2100	Low contro	11/28/2007	2:59:56 PM	3.5	0.7	859	56	6.52%	45.63	
2101	Low contro	11/28/2007	3:04:13 PM	3.6	0.7	772	64	8.29%	58.03	
2102	Low contro	11/28/2007	3:08:32 PM	3.6	0.7	659	62	9.41%	65.86	
		Observed Results		3.57	0.7			6.5 to 9.4%	56.51	45.6 - 65.8
		Expected Results		3.78	0.757			4.1 to 12.1%	61.30	30.7 - 92.0
	FC127 Normal CD4									
2103	Normal Co	11/28/2007	3:12:49 PM	4	1.2	1141	503	44.08%	529.01	
2104	Normal Co	11/28/2007	3:17:06 PM	4.1	1.7	1043	367	35.19%	598.18	
2105	Normal Co	11/28/2007	3:21:26 PM	4.1	1.6	1114	442	39.68%	634.83	
		Observed Results		4.07	1.50			35.7 to 44.08%	587.34	529 to 634.8
		Expected Results		3.98	0.86			44.1 to 57.1%	430.6	323 - 538.3

7.6.2. CBC

CBC results were obtained from Excell 2280 and HT. Figure 4 and 5 illustrate the linear regression analysis of absolute WBC and lymphocyte counts between the two methods. WBC and lymphocyte counts obtained from HT correlated highly (r^2 for WBC = 0.997; r^2 for Lymphocyte = 0.987) with those from the reference Excell 2280.

Figure 4

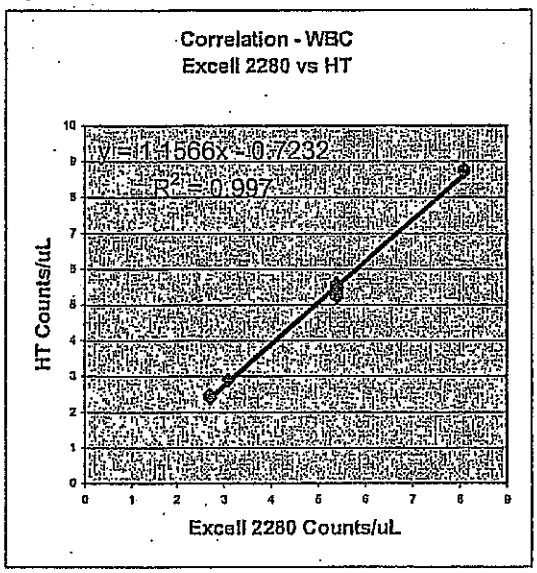
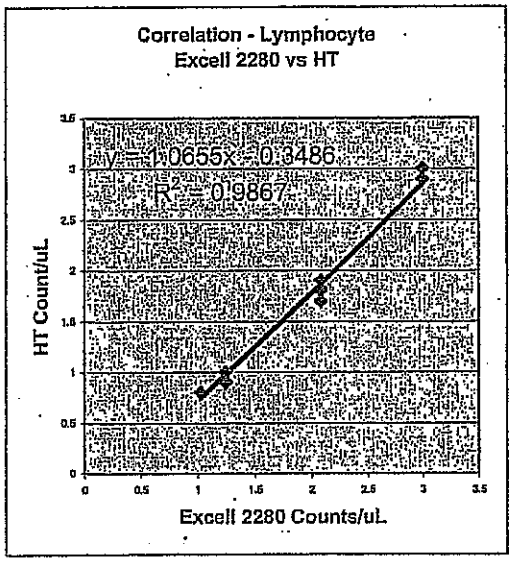


Figure 5



7.6.3. CD4 counts

Flow Cytometry was not available on site to estimate the true values of CD4 percentage and absolute counts in the specimens..

8. Appendix A - Requirements not included in this study

Requirement	Description	Methods
PR-008-012	[Precision RBC] CV% <1% at 5M/u	Not tested
PR-008-015	[Precision PLT] CV% <3% at 250K/uL	Not tested
PR-008-008	[Precision of Monocyte] CV% at 7% is <±7% at WBC count >8000/uL	Not tested

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PR-008-010	[Precision of Eosinophil] CV% at 7% is <7% at WBC count >8000/uL	Not tested
PR-008-011a	[Precision of Hgb] <2% at 7 g/dL	Not tested
PR-008-011b	[Reportable Range Hgb] From 3 to 24 g/dL	Not tested
PR-008-013	[Precision MCV] CV% <1% at 90fl	Not tested
PR-008-014	[Reportable Range RDW] CV% <5% at 15%	Not tested
PR-008-016	[Precision MPV] CV% <5% at 10fl	Not tested
PR-008-018 PR-008-019	[UI: Specimen Age: CD4 counts and %] Allow data entry for sample age, draw time, flagging for scatter plots and training	Not tested
PR-008-022b	[Autoloader handling] Accommodate other vacutainers	Not tested
PR-008-023	[UI: worklist] Choice of sequence from menu or separate worklist. Barcode design to determine which sequence to be used	Not tested
PR-008-025a	[Specimen volume] 180 uL for CBC 45 uL for CD4	Not tested.
PR-008-025b	[Specimen volume] Min specimen volume 1.5 mL	Not tested
PR-008-027	[UI: Display] Touch screen	Not tested
PR-008-028	[UI: anti-theft] Security cable for computer	Not tested
PR-008-029a	[UI: printer] B&W printer	Not tested
PR-008-029b	[UI: printer] Color printer optional	Not tested
PR-008-030	[UI: language]	Not tested

	Eng, French, Portuguese, Spanish, Chinese, Thai, Vietnamese and Russian	
PR-008-031	[UI: operation mode] Service mode, Supervisor mode and limited operator mode (with log on)	Not tested
PR-008-032	[UI: operation mode] Barcoded sample and control entry	Not tested
PR-008-033	[UI: operation mode] Barcoded reagent entry and low reagent alarms	Not tested
PR-008-034	[UI: analytical SW] Automated cluster gating	Not tested
PR-008-035	[Control] Levey-Jennings control plots	Not tested
PR-008-037	[UI: operation mode] Appropriate data storage and hardware capability	Not tested
PR-008-038	[UI: data management] UI designed to facilitate easy patient management	Not tested
PR-008-039a	[UI: operation mode] Full automated start up and shutdown after thermal equilibrium	Not tested
PR-008-039b	[UI: operation mode] Thermal equilibrium achieved in <30 minutes	Not tested
PR-008-040	[Control] SW driven internal control for gold reagent activity	Not tested
PR-008-041a	[UI: analytical DW flags] Strict flag criteria for automated SW gating	Not tested
PR-008-041b	[UI: analytical SW flags] Specific flag criteria	Not tested
PR-008-042	[UI: analytical SW alerts] Alerts for flow irregularity and	Not tested

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	instructions how to proceed	
PR-008-043a	[System: operating conditions] Operating Temp 16-32°C Relative humidity 10-90% non-condensing	Not tested
PR-008-043b	[System: reagent] Bulk gold reagent to be remained on the instrument for up to 5 days	Not tested
PR-008-044	[System: operating conditions] 90-250V 47-63 Hz	Not tested
PR-008-045	[UI: operation mode] UPS specified with the ability to finish cycle and shutdown	Not tested
PR-008-046	[Service] No field service of components for PM	Not tested
PR-008-047a	[Service: calibration] Instrument can be calibrated at the factory or by field service or customer	Not tested
PR-008-047a	[Service: calibration] Only WBC can be calibrated	Not tested
PR-008-048a	[System: CD4 reagent] Minimum of 4 months stability at room temp	Not tested
PR-008-048b	[System: CD4 reagent] Minimum of 12 months stability at room temp	Not tested
PR-008-049a	[Service] File download and remote troubleshooting	Not tested
PR-008-049b	[Service] Bidirectional ASTM or equivalent acceptable with "peer to peer" file sharing	Not tested
PR-008-050	[Service] Automated downloadable software upgrades for UI and analytical software	Not tested
PR-008-051	[Service] Easy field service installation	Not tested

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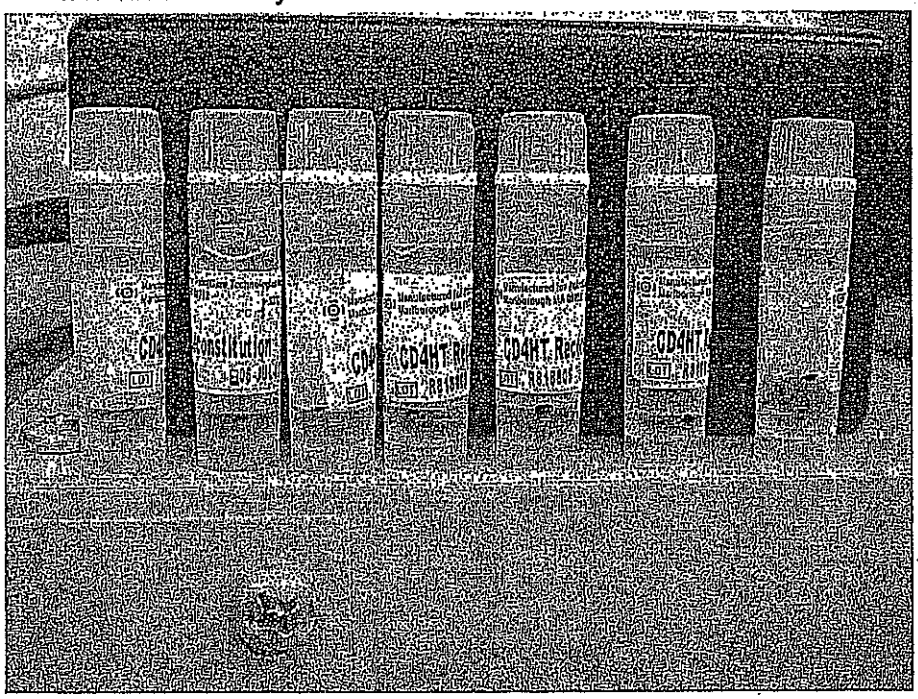
PR-008-053a	[System: regulatory] CE and UL mark	Not tested
PR-008-053b	[System: regulatory] FDA 510(k) for future market expansion	Not tested

9. Appendix B – CD4HT Fill Volume Inconsistency

Seven vials of the CD4HT Reagent depicting different fill volume. Fill lines were indicated by the black markers.



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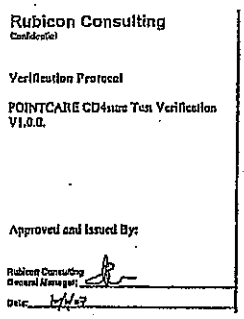
Verification Protocol

POINTCARE CD4sure Test Verification
V1.0.0.

Approved and Issued By:

Rubicon Consulting
General Manager: _____

Date: _____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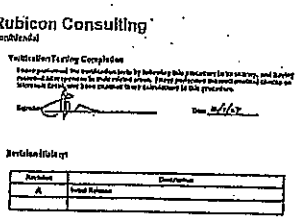
Verification Protocol

POINTCARE CD4sure Test Verification
V1.0.0.

Approved and Issued By:

Rubicon Consulting
General Manager: _____

Date: 1/24/07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Revision	Description
A	Initial Release

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Table of Contents

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1. Purpose:

This Work Instruction establishes the protocol for verification of the POINTCARE CD4sure Lymphocyte Enumeration Assay kit performance to assure completion of design input requirements.

2. Scope:

This Work Instruction applies to the testing of CD4sure assay kit performance on DREW HTc and HTw instrument. Analytical parameters, listed in the document titled "Product Specifications for HT Instrument" are included in this verification procedure and are listed in the Verification Test Matrix (Appendix A)

3. Reference:

- Quality Manual
- QSR 820.70
- ISO 9001 Section 4.9
- Attachment 3 to Annex 1 titled "Synopsis of PointCare Technologies Assay for the Identification of CD4 Positive Lymphocytes: Expression as Percentage of Lymphocyte Count ("CD4%" and CD4 Lymphocyte Count ("CD4 Absolute")
- Attachment 2 to Annex 1 titled "Product Specifications for HT Instrument"
- Reference method for CD4 count and percentage

4. Materials Needed:

- DREW HTc and HTw Instruments (Release xxxxxxxxx)
- POINTCARE CD4sure Lymphocyte Enumeration Assay kit (Release xxxxxxxxx)
- Printer
- Controls Material
- Calibrator Material
- EDTA whole blood samples
- Reference method
- DREW HTc and HTw Instruments Operator's manual (rev xxxxxx)
- POINTCARE CD4sure Lymphocyte Enumeration Assay kit product insert (rev xxxxxx)

5. Equipment and Materials:

- Hematology Reference – EXCELL2280 Instrument
- Drew HT Instrument
- Pointcare CD4 Immunolabeling reagents
- Pointcare Accelerant
- HT CD4 Lysing reagents
- R&D System - CD4 high and low controls

6. Experiment Design

6.1. Counts and Percent correlations between test and reference instruments

6.1.1. Obtain one 50 mL EDTA blood

6.1.2. Creates contrived specimen that represents CD4 count of 200/uL and, if possible, specimens with counts at 400, 800 and 100/uL range.

6.1.3. Test specimens following procedures described in Section 9 (reference) and 10 (test).

6.2. Expected Results

6.2.1. WBC counts

6.2.1.1.Correlation between HT and Hematology reference

6.2.1.2.Precision at low and medium counts

6.2.2. Lymphocyte counts and percentage

6.2.2.1.Correlation between HT and Hematology reference

6.2.2.2.Precision at low and medium counts

6.2.3. Monocyte counts and percentage

6.2.3.1.Correlation between HT and Hematology reference

6.2.3.2.Precision at low and medium counts

6.2.4. CD4+ Monocyte counts and percentage

6.2.4.1.Counts and percentage from HT only, no Flow Cytometry reference available

6.2.4.2.Precision from HT only, no Flow Cytometry reference available

6.2.5. CD4+ lymphocyte counts and percentage

6.2.5.1.Counts and percentage from HT only, no Flow Cytometry reference available

6.2.5.2.Precision at low and medium counts

6.3. Analyses

6.3.1. Regression analysis and /or paired t test between HT and Hematology reference on:

6.3.1.1.WBC

6.3.1.2.Lymphocyte counts and percentage

6.3.1.3.Monocyte counts and percentage

6.3.2. Precision analysis on HT:

6.3.2.1.WBC

6.3.2.2.Lymphocyte counts

6.3.2.3.Monocyte counts

6.3.2.4.CD4 Monocyte counts

6.3.2.5.CD4 Lymphocyte counts at 200/uL (low) and a moderate level

7. Correlation between Test Instrument and Reference Instrument

7.1. Obtain data from reference instruments

7.1.1. Specimens needed:

- 1 to 3 low CD4 counts: EDTA whole blood with CD4 counts of less than 200 per uL.
- 1 to 3 medium CD4 counts: EDTA whole blood with CD4 counts between 201 and 600 per uL.
- 1 to 3 high CD4 counts: EDTA whole blood with CD4 counts of greater than 600 per uL.

- Alternatively, creates contrived specimens with varying concentrations of CD4 counts

7.1.2. Obtain absolute WBC counts in test specimen using the reference Hematology instruments

7.1.3. Obtain lymphocyte percentage in test specimen using the reference Hematology instruments

7.1.4. Review histograms from the Hematology instrument for consistent light scatter and fluorescence patterns prior to reporting data

7.1.5. Obtain CD4 percentage in test specimen using the reference Flow Cytometry instruments

7.1.6. Review histograms from the Flow Cytometry instrument for consistent light scatter and fluorescence patterns prior to reporting data

7.1.7. Calculate lymphocyte counts

7.1.8. Calculate CD4 counts

7.1.9. Entry date in Date Entry Form – Reference Data (see Appendix B)

7.2. Obtain cell counts from the test instrument

7.2.1. Specimens needed:

- 2 to 3 low CD4 counts: EDTA whole blood with CD4 counts of less than 200 per uL.
- 2 to 3 medium CD4 counts: EDTA whole blood with CD4 counts between 201 and 600 per uL.
- 2 to 3 high CD4 counts: EDTA whole blood with CD4 counts of greater than 600 per uL.
- Alternatively, creates contrived specimens with varying concentrations of CD4 counts

7.2.2. Test each aliquot in replicates of 3.

7.2.3. Obtain lymphocyte counts from impedance (A)

7.2.4. Obtain CD4 positive lymphocyte counts from the CD4 positive cluster (B)

7.2.5. Obtain CD4 negative lymphocyte counts from the CD4 negative cluster (C)

7.2.6. Calculate CD4 percentage D = B/(B+C)

7.2.7. Calculate CD4 counts E = A * D

7.2.8. Entry date in Date Entry Form – Test Data (see Appendix C)

7.3. Analysis: determine agreement between the test and reference instruments

7.3.1. Linear regression analysis: For each pair of data, plot test cell counts on Y axis and reference cell counts on X axis. Calculate correlation coefficient and linear regression analysis between test and reference data.

7.3.2. Bland-Altman Plot: For each pair of data, plot test the mean of the values between the two methods against the difference between the two methods on the Y-axis. The mean difference between the two methods (bias) and its 95% confidence intervals, and the limits of agreement, defined as bias ± 2 standard deviation.

8. Precision Studies

8.1. Specimens needed:

- One CD4 specimen with CD4 counts of 200 (±10%) per uL. Divide blood into 3 equal aliquots of at least 2 mL each.

8.2. Test each aliquot in replicates of 10.

8.2.1. Obtain lymphocyte counts from impedance (A)

8.2.2. Obtain CD4 positive lymphocyte counts from the CD4 positive cluster (B)

8.2.3. Obtain CD4 negative lymphocyte counts from the CD4 negative cluster (C)

8.2.4. Calculate CD4 percentage D = B/(B+C)

8.2.5. Calculate CD4 counts E = A * D

8.2.6. Entry date in Date Entry Form – Test Data (see Appendix C)

8.3. Analysis: calculate mean and standard deviation from all combined runs.

9. Accuracy of Absolute CD4 Counts and Percentage

10. Appendix A - Verification Test Matrix

Requirement	Description	Methods	Results	Remarks
PR-008-003	[Precision CD4 count] A maximum of ±25/uL at CD4 counts of 200/uL	Tested		
PR-008-004	[Precision of CD4%] A max of ±2% at 15% lymph and lymph counts of > 1500/uL	Tested		
PR-008-0043c	[System: reagent] Heater will be needed for gold reagent	Tested		
PR-008-006	[Precision of WBC] <2% at WBC counts of 8000/uL	Tested		
PR-008-007	[Precision of Lymph] <3% at Lymphocyte counts of 2000/uL	Tested		
PR-008-017	[Specimen Age CD4 counts and %] Sample age up to 8 hrs	Tested		
PR-008-0052	[System: CD4 reagent] Lyophilized or desiccated bulk gold reagent easily reconstituted by unskilled technician	Observed		
PR-008-021	[Autoloader Throughput] Autoloader works for 1 hour or processes 30 specimens unattended	Observed		
PR-008-022a	[Autoloader handling] Accommodate standard 5 mL vacutainers	Observed		

PR-008-024	[System: 5 pt WBC Diff + CD4] 1st pass – WBC Diff without immunogold 2nd pass – CD4% with immunogold	Observed		
PR-008-026	[Autoloader: cap piercing] Cap piercing capability	Observed		
PR-008-036	[Controls] Control materials for CD4 and CD4% in capped tubes with barcodes	Observed		
PR-008-005	[Precision of CD4%] CD4 monocytes excluded from analysis	Observation		
PR-008-003	[Reportable Range CD4] From 50 to 6000/uL	Not tested		
PR-008-0043a	[System: operating conditions] Operating Temp 16-32°C Relative humidity 10-90% non-condensing	Not tested		
PR-008-0043b	[System: reagent] Bulk gold reagent to be remained on the instrument for up to 5 days	Not tested		
PR-008-0044	[System: operating conditions] 90-250V 47-63 Hz	Not tested		
PR-008-0045	[UI: operation mode] UPS specified with the	Not tested		

	ability to finish cycle and shutdown			
PR-008-0046	[Service] No field service of components for PM	Not tested		
PR-008-0047a	[Service: calibration] Instrument can be calibrated at the factory or by field service or customer b	Not tested		
PR-008-0047a	[Service: calibration] Only WBC can be calibrated	Not tested		
PR-008-0048a	[System: CD4 reagent] Minimum of 4 months stability at room temp	Not tested		
PR-008-0048b	[System: CD4 reagent] Minimum of 12 months stability at room temp	Not tested		
PR-008-0049a	[Service] File download and remote troubleshooting	Not tested		
PR-008-0049b	[Service] Bidirectional ASTM or equivalent acceptable with "peer to peer" file sharing	Not tested		
PR-008-0050	[Service] Automated downloadable software upgrades for UI and analytical software	Not tested		
PR-008-0051	[Service] Easy field service installation	Not tested		

PR-008-0053a	[System: regulatory] CE and UL mark	Not tested		
PR-008-0053b	[System: regulatory] FDA 510(k) for future market expansion	Not tested		
PR-008-008	[Precision of Monocyte] CV% at 7% is <±7% at WBC count >8000/uL	Not tested		
PR-008-009	[Precision of Neutrophil] CV% <60% is <3% at WBC count >8000/uL	Not tested		
PR-008-010	[Precision of Eosinophil] CV% at 7% is <7% at WBC count >8000/uL	Not tested		
PR-008-011a	[Precision of Hgb] <2% at 7 g/dL	Not tested		
PR-008-011b	[Reportable Range Hgb] From 3 to 24 g/dL	Not tested		
PR-008-012	[Reportable Range RBC] CV% <1% at 5M/uL	Not tested		
PR-008-013	[Reportable Range MCV] CV% <1% at 90fl	Not tested		
PR-008-014	[Reportable Range RDW] CV% <5% at 15%	Not tested		
PR-008-015	[Reportable Range PLT] CV% <3% at 250K/uL	Not tested		
PR-008-016	[Reportable Range MPV] CV% <5% at 10fl	Not tested		
PR-008-018	[UI: Specimen Age: CD4 counts and %]	Not tested		

PR-008-019	Allow data entry for sample age, draw time, flagging for scatter plots and training			
PR-008-020	[System Throughput] 4.5 minutes per specimen	Not tested		
PR-008-022b	[Autoloader handling] Accommodate other vacutainers	Not tested		
PR-008-023	[UI: worklist] Choice of sequence from menu or separate worklist. Barcode design to determine which sequence to be used	Not tested		
PR-008-025a	[Specimen volume] 180 uL for CBC 45 uL for CD4	Not tested		
PR-008-025b	[Specimen volume] Min specimen volume 1.5 mL	Not tested		
PR-008-027	[UI: Display] Touch screen	Not tested		
PR-008-028	[UI: anti-theft] Security cable for computer	Not tested		
PR-008-029a	[UI: printer] B&W printer	Not tested		
PR-008-029b	[UI: printer] Color printer optional	Not tested		
PR-008-030	[UI: language] Eng, French, Portuguese, Spanish, Chinese, Thai,	Not tested		

	Vietnamese and Russian			
PR-008-031	[UI: operation mode] Service mode, Supervisor mode and limited operator mode (with log on)	Not tested		
PR-008-032	[UI: operation mode] Barcoded sample and control entry	Not tested		
PR-008-033	[UI: operation mode] Barcoded reagent entry and low reagent alarms	Not tested		
PR-008-034	[UI: analytical SW] Automated cluster gating	Not tested		
PR-008-035	[Control] Levey-Jennings control plots	Not tested		
PR-008-037	[UI: operation mode] Appropriate data storage and hardware capability	Not tested		
PR-008-038	[UI: data management] UI designed to facilitate easy patient management	Not tested		
PR-008-039a	[UI: operation mode] Full automated start up and shutdown after thermal equilibrium	Not tested		
PR-008-039b	[UI: operation mode] Thermal equilibrium achieved in <30 minutes	Not tested		

PR-008-040	[Control] SW driven internal control for gold reagent activity	Not tested		
PR-008-041a	[UI: analytical DW flags] Strict flag criteria for automated SW gating	Not tested		
PR-008-041b	[UI: analytical SW flags] Specific flag criteria	Not tested		
PR-008-042	[UI: analytical SW alerts] Alerts for flow irregularity and instructions how to proceed	Not tested		

11. Appendix B – Data Entry Form – Reference Data

Reference Hematology Instrument # _____
Reference Flow Cytometry Instrument # _____
Date of Experiment _____

Anticipated CD4 Range	Specimen ID	Date of blood Drawn

If natural specimens are not available, contrived specimens can be used

Red = calculated values

CD4 range	Specimen ID	Run #	WBC Count /mL	Lymph %	Lymph Count /mL	CD4 %	CD4 Lymoh /mL	CD4 Mono /mL
		1						
		2						
		3						

12. Appendix C – Data Entry Form – Test Data

Drew HT Instrument # _____
Date of Experiment _____

Anticipated CD4 Range	Specimen ID	Date of blood Drawn

If natural specimens are not available, contrived specimens can be used

Red = calculated values

CD4 range	Specimen ID	Run #	Lymph Count /mL (A)	CD4 Positive Lymph (B	CD4 Negative Lymph (C)	CD4 % (D)	CD4 Counts (E)
		1					
		2					
		3					

13. Verification Testing Completion

I have performed the verification tests by following this procedure in its entirety, and having recorded all responses in their related areas. I have performed the mathematical checks on Microsoft Excel, and have attached these calculations to this procedure.

Signature _____ Date _____

14. Revision History:

Revision	Description
A	Initial Release

EXHIBIT 26

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

----------X

DREW SCIENTIFIC, INC.,

Plaintiff, Case No. 08 CV 1490-AKH

-vs-

POINTCARE TECHNOLOGIES, INC.,

Defendants.

----------X

DEPOSITION OF HERBERT CHOW, Ph.D.

New York, New York

March 25, 2008

Reported by:

Bonnie Pruszynski, RMR

JOB NO. 15871

to do. If it says you have to do revisions, you have to do accuracy, you have to do correlation, you then you design your test plan accordingly.

And I believe most of the methods I use are common to any test laboratory, of someone who is skilled in the art. So, there is nothing, nothing that I have to invent. It's -- it's off-the-shelf methods.

Q Now, if I followed you, you decided which specifications to test based on your understanding of the status of the HT instrument in the development process in general terms; correct?

A Correct.

Q If you can bring me back to the tutorial you gave me before about the various steps, what step in the design development process was this instrument when you were asked to test it?

A The intended use of the instrument is to count CD4 and to estimate CD4 percent. So, obviously I will need -- I will need the necessary software to do that. In order get a good CD4, accurate CD4 count, I will need an accurate

lymphocyte count. And to get a good lymphocyte count, I will need an accurate total white blood cell count, the total WBC count. So, that is the train of thought.

As to whether I include anything else other than those elements, it's icing on the cake.

It's good to test at this point, but if the software is not ready, if they are not, if they are not pertaining to giving me the CD4 results, then I have the freedom to either include them or exclude them. My practice will be I will include them, but I may not analyze them, because they have nothing to do with CD4 cell count.

Q I think my inartful question wasn't clear.

Before, when we had the tutorial about the different steps of the process from breadboard, and all the different prototype stages, my question was just when they handed you an HT, where was it in that process?

A Oh, if I -- where would I classify HT in terms of whether it's a pre-- preproduction prototype, engineering prototype or a breadboard?

Q Or any other category or step in the

process.

A Given the message to me, that the final algorithm in this stage, I would assume it's the CD4 algorithm is not complete, I would say it has to be a preclinical instrument.

Well, actually it's probably before that. When I say preclinical, it's an instrument that I am allowed to collect clinical data.

If someone told me the final software is not quite ready, which is telling me that, you know, this piece of equipment is not ready to go collect clinical data. So, it's definitely not preclinical prototype. It's got to be something before that.

And something before that, it would be -- did I say it is not a preclinical prototype?

Q Yes.

A No, let me stand corrected.

It is not a clinical prototype. It has to be a preclinical prototype or engineering prototype.

Q Do you know which it was?

A At the time, before I went to the site, I did not know, because the only difference

between the two is what extent the pilot manufacturings have gone through the thought process of how to manufacture the product. So, if they haven't gone through the manufacturing process, then it's an engineering prototype; if they have gone through some careful pilot build methodology, it would be classified as a preclinical prototype.

Q Now, you have seen and tested the HT; right?

A Yes.

Q So what was it?

A I believe it is somewhere in-between. It's probably closer to a preclinical prototype than an engineering prototype.

Q Why do you say that?

A It's a complicated piece of equipment. Someone have organized the manufacturing process, the wiring and all that seems like they are in the right place. There are a lot of subassemblies already gone through packaging, so there is not like a wiring hanging out, the wire tire is crooked. Someone must have done some manufacturing packaging. So, even